

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Public Service Insurance Company,	:	
	:	
Plaintiff,	:	Docket No.
v.	:	
	:	CLASS ACTION COMPLAINT
Janssen Pharmaceuticals, Inc.;	:	
Johnson & Johnson, Inc.; Noramco,	:	Jury Trial Demanded
Inc.; Ortho-McNeil-Janssen;	:	
Pharmaceuticals, Inc.; Janssen	:	
Pharmaceutica, Inc.; Cephalon, Inc.;	:	
Teva Pharmaceutical Industries, Ltd.;	:	
Teva Pharmaceuticals USA, Inc.;	:	
Allergan PLC; Actavis Kadian LLC;	:	
Watson Pharmaceuticals, Inc.;	:	
Actavis Pharma, Inc.; Endo Health	:	
Solutions, Inc.; Endo	:	
Pharmaceuticals, Inc. d/b/a Endo	:	
Generic Products; Endo International	:	
plc; Par Pharmaceutical Companies,	:	
Inc. d/b/a Par Pharmaceutical;	:	
Richard S. Sackler;	:	
Jonathan D. Sackler; Mortimer D.A.	:	
Sackler; Kathe A. Sackler; Ilene	:	
Sackler Lefcourt; Beverly Sackler;	:	
Theresa Sackler; David A. Sackler;	:	
Trust for the Benefit of Members of	:	
the Raymond Sackler Family;	:	
The P.F. Laboratories, Inc.; Stuart D.	:	
Baker; American Academy of Pain	:	
Medicine, Inc.; American Geriatrics	:	
Society; American Pain Society, Inc.;	:	
AmerisourceBergen Drug	:	
Corporation; Bellco Drug Corp.;	:	
Cardinal Health, Inc.; Kinray, LLC;	:	
McKesson Corporation; Rochester	:	
Drug Cooperative, Inc.;	:	
Bellco Drug Corp.; Rochester Drug	:	
Cooperative, Inc.; Walgreens Co.; and	:	
Walgreens Boots Alliance, Inc.,	:	
	:	
Defendants.	:	

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NATURE OF THE ACTION

1. Plaintiff Public Service Insurance Company (“Plaintiff”), on behalf of itself and for all other similarly situated workers’ compensation insurers and self-insured employers in the United States (including territories and possessions), which pay for and provide injured workers’ compensation benefits, including medical treatment, prescription, disability, and death benefits (collectively “Workers’ Compensation Payors” or the “Class”), brings this action against the Manufacturing, Front Group, and Distributor Defendants (collectively “Defendants”), as defined below. The claims and causes of action against Defendants are based upon Plaintiff’s business records and institutional knowledge as to matters relating to it, and its losses complained of, and upon information provided to it from its counsel’s investigation, the findings and reports of government agencies and industry research organizations, as well as the records, proceedings, and reports in related legal proceedings brought against the Defendants and their affiliates, all of which Plaintiff believes to be true.

2. Defendants actively misrepresented and/or suppressed material information about the safety and efficacy of opioid drugs, and/or violated various duties regarding the distribution of controlled substances, which permitted and resulted in massive diversions of prescription opiates to enter illicit distribution channels.

3. Defendants’ activities have harmed many people, families, businesses, organizations and government bodies, including Plaintiff and other Workers’ Compensation Payors.

4. Defendants, individually and in concert, did this to increase the market for opioid pain medications and to in turn garner tremendous profits, returns on investments and compensation.

5. Central to Defendants’ fraudulent scheme, which resulted in ultimately generating what public health authorities have declared to be a national opioid medication epidemic or crisis, was that third-party payors such as Plaintiff, would pay for these addictive drugs where licensed prescribers wrote a patient a prescription regardless of what the U.S. Food and Drug Administration (“FDA”) actually approved them for, which was very limited.

6. Defendants did what they did—developed, expanded and maintained a national market demand for opioid drugs for uses and indications well beyond what the FDA approved in the drugs’ labelling—because third-party payors would cover the cost of opioid pain medications if doctors and other licensed health care providers prescribed them. That Plaintiff and other Workers’ Compensation Payors would cover the costs of these prescriptions for injured workers who, as is often the case, developed chronic pain conditions was both the foreseeable and intended consequence of Defendants’ fraudulent marketing scheme (hereinafter the “Opioid Marketing Enterprise”). Indeed, the very point of Defendants’ scheme was to obtain payment for opioid prescriptions from third-party payors such as the Workers’

Compensation Payors. Indeed, if third-party payors such as Plaintiff and the Workers' Compensation Payors Class did not cover the cost of the opioid pain medications as a prescription benefit, none of the Defendants would have had any incentive to engage in the multifaceted fraudulent marketing scheme at the heart of this case.

7. While many individuals, families, groups, institutions and government organizations have been profoundly harmed by the prescription opioid epidemic besieging our nation, Plaintiff and other Workers' Compensation Payors are without question, one group which has been directly, massively, and disproportionately, financially hard hit by Defendants' fraudulent marketing and distribution scheme.

8. Workers' Compensation Payors were (and continue to be) forced to shoulder a wide array of substantial costs relating to the prescription of opioids to treat injured workers, the payment of which, has and continues to directly and foreseeably harm Plaintiff and the other Workers' Compensation Payors.

9. Many of the benefits Workers' Compensation Payors are required to pay injured workers and/or their families distinguish them from other third-party payors. In addition to paying for the full cost of the opioid pain medications themselves (as injured workers do not pay deductibles or co-pays)—an amount totaling in the millions of dollars for Plaintiff alone—are the medical care costs associated with multiple doctor/nurse practitioner visits to obtain opioid prescriptions or for monitoring/testing the injured worker while on the drugs; treating the injured worker for a wide array of Opioid Use Disorders that come from

using opioids to treat chronic pain, such as the occurrence of other conditions or injuries related to taking opioids, addiction treatment, and overdoses. On top of these medical costs, unlike other third-party payors, Workers' Compensation Payors are required to also pay for an array of costly workers' compensation benefit items that others affected by the epidemic are not required to bear. These include death benefit payments to the families or estates of injured workers that sustained fatalities due to opioid use, and, significantly, the cost of prolonged temporary disability income benefit payments that must be paid to injured workers when they are unable to work.

10. The longer duration of disability income payments that Workers' Compensation Payors pay to injured workers that were prescribed opioids to treat chronic pain from their work injuries is a recognized and demonstrated fact, and one responsible for the Workers' Compensation Payors sustaining very substantial losses. The positive association between opioid drugs and longer duration of workers disability payments has been scientifically established through statistical studies conducted by a number of different investigators.

11. A 2018 research report published by the Workers' Compensation Research Institute ("WCRI"),¹ which investigated whether opioid drug

¹ The WCRI is an independent, not for profit research organization, dedicated to providing objective data and analysis to assist stakeholders interested in making improvements to the workers' compensation system, including employers, insurers and labor unions.

prescriptions alone caused prolonged duration of temporary disability payments, references a number of them:

Many studies found longer duration of temporary disability benefits for low back pain cases with opioid prescriptions. Compared with workers without opioid prescriptions, the studies reported longer duration of temporary disability when workers had opioid prescriptions for over seven days (Mahmud et al., 2000), when they had more than seven days of opioid prescriptions within six weeks after an injury (Franklin et al., 2008), when they had more than seven opioid prescriptions (Swedlow et al., 2008), when they had any filled prescriptions for opioids (Volinn et al., 2009), or when they had opioid prescriptions within 15 days of an injury (Webster et al., 2007; Shraim et al., 2015). These studies typically found stronger relationships with duration of temporary disability for larger numbers of prescriptions or amounts of opioids, longer-term filling of opioid prescriptions, or more potent opioids (Schedule II versus Schedule III or IV). Similar evidence was also reported for a broader sample of workers' compensation cases. Gross et al. (2009) used data on workers' compensation claims in Alberta, Canada, and showed that workers who received early opioid prescriptions stayed on disability benefits longer; the exit rate from benefits was double for those not prescribed early opioids versus those prescribed early opioids.²

12. The results of WCRI's 2018 study on the impact of opioid prescriptions on the duration of workers' disabilities determined that a causal relation existed. The Institute's researchers examined data on worker low back injury claims from 28 states and found that longer-term opioid prescriptions resulted in temporary disability payment durations that were *more than triple* the duration of claimants with no opioid medication prescriptions.³

² Bogdan Savych, et al, The Impact of Opioid Prescriptions on Duration of Temporary Disability, Workers' Compensation Research Institute pg. 13 (2018).

³ *Id.* at 39.

13. Longer worker disability duration has translated into huge amounts of benefit dollars paid by Plaintiff and other Workers' Compensation Payors, especially when other statistics compiled by WCRI on the prevalence of opioid prescriptions are considered.

14. Statistics the WCRI has compiled from workers' compensation claims data further demonstrate that opioids were widely prescribed and filled by injured workers. Approximately 55%–85% of injured workers with more than seven days of lost time from work received opioids for pain relief⁴—and a significant proportion of these injured workers received opioids on a longer-term basis⁵:

15. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.⁶ Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening

⁴ Dongchun Wang, *Longer-Term Dispensing of Opioids, 4th Edition*, Workers' Compensation Research Institute pg. 17 (2017).

⁵ *Id.* at 13.

⁶ Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as "controlled substances". As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

the perception of pain. Opioids also can create a euphoric high, which makes them highly addictive.

16. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.⁷ Throughout this Complaint, “addiction” refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

17. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew—and had known for years—that opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain—that is, pain lasting three months or longer, hereinafter referred to as “chronic pain”—and should not be used in those circumstances, except as a last-resort.

18. Defendants knew that, barring exceptional circumstances, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer.

19. Defendants further knew—and had known for years—that with prolonged use, the effectiveness of opioids in pain management wanes, requiring increases in dosage, which markedly increases the risk of significant side effects and addiction.

20. Defendants also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed

⁷ Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) (“DSM-V”).

settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant. Indeed, the U.S. Food and Drug Administration (“FDA”) has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

21. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea of change in the medical and public perception of opioids that would permit and lead to their use not just for acute and palliative care, but also for longer periods of time to treat more common aches and pains, like those commonly endured by injured workers.

22. Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, set out to and did, in fact, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—became commonplace, as a result.

23. To accomplish this reversal, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat chronic pain; (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids; (c) recruiting prescribing physicians as paid speakers as a means to secure those physicians’ future “brand loyalty” and to extend their reach to all physicians; (d) funding, assisting, encouraging, and

directing certain doctors, known as “key opinion leaders” (“KOLs”), to (i) deliver scripted talks, (ii) draft misleading studies, (iii) present continuing medical education programs (“CMEs”) that were deceptive and lacked balance, and to (iv) serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”) that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

24. These efforts were executed, developed, supported, and directed by Defendants, and designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors, patients and others that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients.

25. At the heart of these efforts were seven primary misleading and unfounded representations that Defendants and the third-parties, with which they teamed, made:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them “pseudoaddiction”;

- falsely claimed withdrawal is easily managed;
- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

26. Through these misleading and unfounded representations, Defendants established a new and far broader market for their potent and highly addictive drugs—the chronic pain market.

27. Defendants persuaded doctors, patients and others, that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and to the contrary, that the compassionate treatment of pain required opioids.

28. There was, and is, no reliable scientific evidence to support Defendants' marketing claims. To the contrary, there was, and is, a wealth of scientific evidence that these claims are simply false.

29. Defendants also deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

30. Even Defendants' KOLs were initially very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far.

31. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the over-prescription of opioids to treat chronic pain, Defendants continue even today, to offer their misleading and unfair marketing claims to justify and defend their conduct and activities.

32. Defendants' efforts were wildly successful in expanding opioid abuse: the United States is now awash in opioids.

33. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for a month.

34. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000.

35. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs.

36. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.

37. Together, opioids generated \$8 billion in revenue for drug companies in 2012. And by 2015, sales of opioids grew further to approximately \$9.6 billion.⁸

⁸ David Crow, *Drugmakers hooked on \$10bn opioid habit*, Financial Times (August 10, 2016).

38. As had been reported by CompPharma, LLC and the Wall Street Journal, Workers' Compensation Payors spent \$ 1.54 billion on opioids in 2015, which amounted to 13% of all spending on opioids in the United States that year.⁹

39. It was Defendants' marketing—and not any medical breakthrough—that spurred the spike in prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic in human, social and financial terms.

40. Indeed, the National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and ***aggressive marketing by pharmaceutical companies.***"¹⁰ As shown herein, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes" are not really independent causative

⁹ *Prescription Drug Management in Workers' Compensation*, CompPharma, LLC (2016), available at https://comppharma.com/wp-content/uploads/2016/10/2016CompPharmaPharmacySurvey.Final_.pdf (accessed on November 14, 2019); Rachel Emma Silverman, *Targeting Opioid Use When Workers Get Hurt*, Wall Street Journal (Nov. 15, 2016), available at <https://www.wsj.com/articles/targeting-opioid-use-when-workers-get-hurt-1479205803> (accessed on December 4, 2019).

¹⁰ America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed November 13, 2019) (emphasis added).

factors but are in fact the direct result of “the aggressive marketing by pharmaceutical companies.”

41. According to the U.S. Centers for Disease Control and Prevention (“CDC”), the nation has been swept up in an opioid-induced “public health epidemic.”¹¹

42. Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One Defendant’s 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008.

43. Defendants’ actions resulted in tremendous numbers of injured workers throughout the country routinely being prescribed opiates for pain relief, which Plaintiff and other Workers’ Compensation Payors paid for as they were obligated to by workers’ compensation laws and their policies.

44. Because Defendants’ engaged in both branded and unbranded marketing to expand the chronic pain market, Defendants are responsible for not only increasing the demand for opioid pain prescriptions for their own medications, but also those of the other Manufacturing Defendants, as well. Therefore, having engaged in unbranded marketing, Defendants are collectively responsible for

¹¹ CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/t20140429.htm> (accessed November 13, 2019).

Plaintiff and the other Workers' Compensation Payors' damages resulting from all opioid pain medications that were prescribed in connection with the treatment of the injured workers' injuries and not for acute pain, surgical recovery, cancer treatment, or end-of-life palliative care.¹²

45. Defendants' actions are not permitted or excused by the fact that their labels may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain.

46. The FDA's approval moreover did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids.

47. Indeed, what makes Defendants' efforts particularly nefarious—and, in fact, dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances.

48. Defendants thus deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs and/or were profoundly damaged by them.

¹² Joe Paduda, *Workers com's top problem drug*, Managed Care Matters (Sept. 27, 20016), *available at* https://www.joepaduda.com/2006/09/27/workers_comps_t_1/ (accessed December 11, 2019); Stephanie Goldberg, *Workers comp sector seeks to curb off-label drug use*, Business Insurance (Jan. 18, 2015), *available at* <https://www.businessinsurance.com/article/00010101/NEWS08/301189979/Workers-comp-sector-seeks-to-curb-off-label-drug-use> (accessed December 11, 2016).

49. Defendants' causal role is not broken by the involvement of doctors who prescribed their medications.

50. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source that doctors could rely on for information and prevented them from making informed treatment decisions.

51. Defendants targeted not only pain specialists, but also primary care physicians ("PCPs"), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements.

52. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

53. Because of the misinformation campaign by Defendants, claimants and their doctors have been deprived of their chance to exercise informed judgment. As a direct and foreseeable result, Plaintiff and other Workers' Compensation Payors have been left to pay for medically unnecessary opioid pain medications—*i.e.*, not for acute pain, surgical recovery, cancer treatment, or end-of-life palliative care—and the attendant costs, including those for opioid addiction treatment as well as disability and death benefits, and thus, have been substantially harmed because of Defendants' fraud.

JURISDICTION AND VENUE

54. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1362 because this action presents a federal question.

55. This Court has supplemental jurisdiction over the state-law causes of action under 28 U.S.C. § 1367 because the state-law claims are part of the same case or controversy.

56. This Court has personal jurisdiction over all Defendants because each Defendant has substantial contacts and business relationships with Pennsylvania, including consenting to be sued in Pennsylvania by registering an agent for service of process and/or obtaining a distributor license, and has purposefully availed itself of business opportunities in Pennsylvania, including by marketing, distributing, or selling prescription opioids in Pennsylvania.

57. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(1) and 1391(b)(2) because numerous Defendants, as described above, reside in, are headquartered in, and/or conduct business in, this judicial district, and because a substantial part of the acts or omissions giving rise to the claims set forth herein occurred in this judicial district, or were directed and controlled from within this judicial district.

PARTIES

I. Plaintiff.

58. Plaintiff Public Service Insurance Company (“Plaintiff” or “PSIC”) is a property/casualty insurance company incorporated under the laws of Illinois and

headquartered in New York. It is licensed to write insurance throughout the United States. At all material times herein, it has provided and paid for workers' compensation benefits to injured claimants throughout the United States, including to injured workers who were prescribed opioid medications that are at issue in this case in California, Connecticut, Illinois, Massachusetts, New Jersey, New York, and Pennsylvania. PSIC has also incurred substantial costs and losses for treating opioid use disorders and for prolonged temporary disability payments resulting from its injured claimants' prescriptions and use of opioids to treat or alleviate chronic non-cancer chronic pain.

59. Plaintiff PSIC assumed the assets and liabilities, including the workers' compensation policies, of Paramount Insurance Company ("PMT"), a New York headquartered property and casualty company, through a merger in 2016. PMT, like PSIC, provided (and continues to provide) workers' compensation benefits to injured workers on behalf of its insured employers.

II. Defendants.

A. Manufacturing Defendants.

60. Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson, Inc. ("Johnson & Johnson"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

61. Johnson & Johnson is the only company that owns over 10 percent of Janssen's stock, and the company corresponds with the FDA regarding Janssen's

products. Johnson & Johnson controls the sale and development of Janssen's drugs, and Janssen's profits inure to Johnson & Johnson's benefit.

62. Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware, and was a wholly owned subsidiary of Johnson & Johnson until July 2016.

63. Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil-Janssen") and Janssen Pharmaceutica, Inc., ("Janssen Pharmaceutica") are both Pennsylvania corporations with their principal places of business in Titusville, New Jersey. Both are now known as Janssen Pharmaceuticals, Inc. These entities—Janssen, Johnson & Johnson, Noramco, Ortho-McNeil-Janssen, and Janssen Pharmaceutica—are collectively referred to herein as "Janssen" unless otherwise specified.

64. At all times relevant hereto, Defendant Janssen conducted substantial and continuous business in Pennsylvania, including the marketing, selling, and distribution of its opioid drugs to claimants in Pennsylvania

65. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs to the claimants of Plaintiff and the Workers' Compensation Payors, and the rest of the nation, including Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

66. Until January 2015, Janssen also developed, marketed, and sold Nucynta and Nucynta ER:

(a) Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Nucynta ER was indicated for the “management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.” The DPN indication was added in August 2012.

(b) Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.”

(c) Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.¹³ Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

67. Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware

¹³ <http://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html> (accessed November 18, 2019)

corporation and wholly owned subsidiary of Teva Ltd. with its principal place of business in Montgomery County, Pennsylvania. Teva Ltd. and Teva USA acquired Cephalon in 2011. Teva Ltd. directs the business practices of Cephalon, and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. These three entities—Teva Ltd., Teva USA, and Cephalon—are referred to as “Cephalon” herein, unless otherwise specified.

(a) At all times relevant hereto, Defendant Cephalon conducted substantial and continuous business in Pennsylvania, including the marketing, selling, and distribution of its opioid drugs to claimants in Pennsylvania

(b) Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, nationally and on information and belief, specifically to claimants of Workers’ Compensation Payors:

(i) Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”

(ii) Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

68. Allergan PLC (“Allergan”) is a public company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis Kadian LLC (“Actavis Kadian”) is a Delaware corporation and subsidiary of Allergan, with its principal place of business in Morristown, New Jersey.

69. Actavis Elizabeth, LLC (“Actavis Elizabeth”) is a Delaware corporation with its principal place of business in Elizabeth, New Jersey. Actavis PLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

70. Actavis PLC acquired Allergan in March 2015, and the company took the Allergan name. Before that, Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) acquired Actavis PLC in October 2012.

71. Watson Laboratories, Inc. (“Watson Labs”) is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan. Actavis Pharma, Inc. (“Actavis Pharma”) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc.

72. Prior to 2016, Allergan was the corporate parent of Actavis, Actavis PLC, Actavis Pharma, Actavis Elizabeth, Actavis Kadian, Watson Pharmaceuticals, and Watson Labs (together, the “Actavis Generics”).

73. In 2016, Teva USA wholly acquired the Actavis Generics. Teva Ltd. now exercises control over these marketing and sales efforts, and the Actavis

Generics products ultimately inure to its benefit. The Actavis Generics are referred to as “Actavis” herein, unless otherwise specified.

(a) At all times relevant hereto, Defendant Actavis conducted substantial and continuous business in Pennsylvania, including the marketing, selling, and distribution of its opioid drugs to claimants in Pennsylvania

(b) Actavis engages in the business of marketing and selling opioids to the claimants of Plaintiff and the Workers’ Compensation Payors, and across the country, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian (morphine sulfate extended release) is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

(c) Prior to April 2014, Kadian was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.” Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

74. Endo Health Solutions, Inc. (“Endo Health Solutions”) is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. d/b/a Endo Generic Products (“Endo Pharmaceuticals”) is a wholly owned subsidiary of Endo Health Solutions and is a Delaware corporation

with its principal place of business in Malvern, Pennsylvania. Endo International PLC is an Irish public limited company, with its U.S. headquarters in Malvern, Pennsylvania.

75. Par Pharmaceutical Companies, Inc. d/b/a Par Pharmaceutical (“Par Pharmaceutical”) is a Delaware corporation with its principal place of business in Chestnut Ridge, New York.

76. Endo Health Solutions acquired Par Pharmaceutical in September 2015. Endo Health Solutions now exercises control over these marketing and sales efforts, and the Par Pharmaceutical products ultimately inure to its benefit. Endo Health Solutions, Endo Pharmaceuticals, Endo International PLC and Par Pharmaceutical are collectively referred to herein as “Endo,” unless otherwise specified.

(a) At all times relevant hereto, Defendant Endo conducted substantial and continuous business in Pennsylvania, including the marketing, selling, and distribution of its opioid drugs to claimants in Pennsylvania

(b) Endo develops, markets, and sells prescription drugs, including the following opioids nationally and specifically to claimants of Plaintiff and the Workers’ Compensation Payors:

(i) Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014,

Opana ER was indicated for the “relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.”

(ii) On June 8, 2017, the FDA requested that Endo Pharmaceuticals remove its opioid medication, reformulated Opana ER (oxymorphone hydrochloride), from the market.¹⁴

(iii) Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the “relief of moderate to severe acute pain where the use of an opioid is appropriate.”

(iv) Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the “management of moderate to moderately severe pain.”

(v) Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the “relief of moderate to moderately severe pain.”

(c) Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and alone accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids nationally and specifically to the claimants of Plaintiff and

¹⁴ Press Release, U.S. Food & Drug Admin., *FDA Requests Removal of Opana ER for Risks Related to Abuse*, (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

the Workers' Compensation Payors, both itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

77. On September 15, 2019 Purdue Pharma L.P. ("Purdue L.P."), a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut, filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York, docketed as Case No. 19-23649. In addition to Purdue L.P., the following affiliated or related companies to Purdue L.P. filed petitions for Bankruptcy protection under Chapter 11 of the Bankruptcy Code in the Southern District of New York which are being jointly administered: Purdue Pharma Inc., ("Purdue Inc."), Purdue Transdermal Technologies L.P., Purdue Pharma Manufacturing L.P., Purdue Pharmaceuticals L.P., Imbrium Therapeutics L.P., Adlon Therapeutics L.P., Greenfield BioVentures L.P., Seven Seas Hill Corp., Ophir Green Corp., Purdue Pharma of Puerto Rico, Avrio Health L.P., Purdue Pharmaceutical Products L.P., Purdue Neuroscience Company, Nayatt Cove Lifescience Inc., Button Land L.P., Rhodes Associates L.P., Paul Land Inc., Quidnick Land L.P., Rhodes Pharmaceuticals L.P., Rhodes Technologies, UDFLP, SVC Pharma LP, and SVC Pharma Inc. (collectively the "Bankrupt Purdue Companies"). Due to the automatic stay imposed by Section 362 of the Bankruptcy Code, none of the potentially responsible Bankrupt Purdue Companies are joined as a defendant.

78. Purdue L.P. is the main operating entity for the Purdue Pharmaceutical enterprise. It is, and was, at all times material herein, managed and operated by its general partner, Purdue Inc., which in turn is and was governed by Purdue Inc.'s Board of Directors. Purdue L.P. and its affiliates and subsidiaries are owned by various trusts for the benefit of members of the two Sackler Families who together are identified below and named as constituents of the "Purdue-Related Additional Defendants".

79. Pursuant to a November 6, 2019 Order of the United States Bankruptcy Court for the Southern District of New York, a preliminary injunction was entered pursuant to § 105(a) of the Bankruptcy Code and Rule 7065 of the Bankruptcy Rules as to the Purdue-Related Additional Defendants named herein with respect to cases then filed and pending, which this matter is not one and accordingly, they may and have been named and joined herein as co-defendants in this matter. In entering that Order, the Bankruptcy Court found that the representatives of the Raymond Sackler and the Mortimer Sackler families agreed on the record "to toll all applicable statutes of limitations and similar time limits on the commencement of Additional Actions against any member of the Sackler Families . . . for the duration of this preliminary injunction." Docket No. 19-08289, Doc. 105. The Order further provides that Bankruptcy Court reserved discretion to extend its injunction to subsequently filed "Additional Actions".

80. Purdue Inc., the managing general partner of Purdue L.P. is a New York corporation with its principal place of business in Stamford, Connecticut. The

Purdue Frederick Company Inc. (“Purdue Frederick”), which did not file a bankruptcy petition, is named herein as a defendant, is a New York corporation with its principal place of business in Stamford, Connecticut. Rhodes Pharmaceuticals, L.P. (“Rhodes”), which did file a bankruptcy petition is subject to Bankruptcy Code §362 stay and accordingly is not named herein as defendant, is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. These four entities are collectively referred to herein as “Purdue” unless otherwise specified.

(a) At all times relevant hereto, Purdue conducted substantial and continuous business in Pennsylvania, including the marketing, selling, and distribution of its opioid drugs to claimants in Pennsylvania

(b) Purdue is and was primarily engaged in the manufacture, promotion, sale, and distribution of opioids including the following:

(i) OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist¹⁵ tablet first approved in 1995 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014,¹⁶

¹⁵ An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

¹⁶ The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens’ petition to FDA by doctors. The changes were intended to clarify the existing obligation to “make an individualized assessment of patient needs.” The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing “Monitor for signs of misuse, abuse, and addiction” to “[Drug name]

OxyContin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

(ii) MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, MS Contin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

(iii) Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the “management of pain in patients where an opioid analgesic is appropriate.”

(iv) Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the “relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief.”

exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death.” Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., *Labeling Supplement and PMR [Post-Marketing Research] Required* (Sept. 10, 2013), <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf> (accessed November 12, 2019).

(v) Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the “management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Butrans was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

(vi) Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

(vii) Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

(c) The Purdue-Related Additional Defendants are entities and individuals associated with Purdue L.P., Purdue Inc., and The Purdue Frederick Company, Inc. These three entities are members of a worldwide group of associated companies all of which are owned and controlled, directly or indirectly through family trusts and holding companies, 50% by the widow and descendants of Mortimer D. Sackler (“Mortimer Sackler Family”) and 50% by the widow and

descendants of Raymond R. Sackler (“Raymond Sackler Family”) (together the Mortimer Sackler Family and the Raymond Sackler Family are referred to as the “Sackler Families”). At all relevant times, the Sackler Families jointly managed and controlled all of the associated companies that the two families owned through trusts and holding companies. Each of the Purdue-related individuals and entities named herein as Additional Defendants knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in the Complaint; none is named merely because of his, her, or its status as a shareholder, limited partner, member of a limited liability company, or beneficiary of a trust.

(d) At all times relevant hereto, the Purdue-Related Additional Defendants conducted substantial and continuous business in Pennsylvania, including the marketing, selling, and distribution of its opioid drugs to claimants in Pennsylvania

(e) Purdue has been sued by many plaintiffs for the role it played in creating the prescription opioid epidemic. The Purdue entities originally and now in Bankruptcy lacked sufficient assets to satisfy their liabilities to those plaintiffs, other creditors, Plaintiff, and members of the Class herein because billions of dollars of profits from the Purdue enterprise’s sale of opioids has been distributed to the Sackler Families since the 1980s. Accordingly, Plaintiff is joining as defendants the following members of the Sackler Families and their controlled entities who knowingly participated in the wrongdoing of Purdue as alleged in this Complaint, and who knowingly received the benefits of that wrongdoing:

(i) Defendant Richard S. Sackler resides in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990's, served as a member of the Board of Directors of Purdue and Purdue-related entities.

(ii) Defendant Jonathan D. Sackler resides in Fairfield County, Connecticut. He is a son of Raymond Sackler and has been a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

(iii) Defendant Mortimer D.A. Sackler resides in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

(iv) Defendant Kathe A. Sackler resides in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

(v) Defendant Ilene Sackler Lefcourt resides in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

(vi) Defendant Beverly Sackler resides in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

(vii) Defendant Theresa Sackler resides in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

(viii) Defendant David A. Sackler resides in New York County, New York. He is the son of Richard Sackler (the grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

(ix) Defendant Rhodes Pharmaceuticals Inc. (“Rhodes Pharma Inc.”) is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin which is manufactured by PPNC.

(x) Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the “Raymond Sackler Trust”) is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related Additional Defendants and the recipient of 50% of the profits from the sale of opioids by Purdue and the Purdue-related Additional Defendants.

(xi) Defendant The P.F. Laboratories, Inc. (“PF Labs”) is a New Jersey corporation with its principal place of business located in Totowa, New Jersey. It was, at relevant times, engaged in the business of manufacturing OxyContin for Purdue. At all relevant times, PF Labs has been beneficially owned, managed, and controlled by Defendant Sackler Family members.

(xii) Defendant Stuart D. Baker is a natural person residing in Suffolk County, New York. He has served as a senior executive of, and/or counsel to,

Purdue, Purdue-related entities, and members of the Sackler Families since the 1990s.

81. Actavis, Cephalon, Endo, Janssen, and the Purdue-Related Additional Defendants as described above are collectively referred to as the “Manufacturing Defendants”.

B. Front Group Defendants.

82. The American Academy of Pain Medicine, Inc. (“AAPM”) is a 501(c)(6) tax exempt organization with its principal place of operation in Chicago, Illinois. According to one of its more recent Form 990 filings with the Internal Revenue Service, AAPM’s purpose is to “optimize the health of patients and eliminate the major public health problem of pain by advancing the practice and the specialty of pain medicine.”

(a) At all times relevant hereto, Defendant AAPM conducted substantial and continuous business in Pennsylvania, including the marketing and promotion of opioid drugs in Pennsylvania.

83. The American Geriatrics Society (“AGS”) is a 501(c)(3) tax exempt organization with its principal place of operations in New York, New York. According to its more recent Form 990 filing with the Internal Revenue Service, AGS’s purpose is to “[i]mprove the health, independence[, and] quality of life of all older people[.]”

(a) At all times relevant hereto, Defendant AGS conducted substantial and continuous business in Pennsylvania, including the marketing and promotion of opioid drugs in Pennsylvania.

84. The American Pain Society, Inc. (“APS”) is a 501(c)(3) tax exempt organization with its principal place of operations in Chicago, Illinois. According to one of its more recent Form 990 filings with the Internal Revenue Service, APS’s purpose is to “increase the knowledge of pain and transform public policy and clinical practice.”

(a) At all times relevant hereto, Defendant APS conducted substantial and continuous business in Pennsylvania, including the marketing and promotion of opioid drugs in Pennsylvania.

85. AAPM, AGS and PSA are collectively referred to as the “Front Group Defendants”.

C. Distributor Defendants.

86. AmerisourceBergen Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen operates a distribution center in Romeoville, Illinois.

(a) At all times relevant hereto, Defendant AmerisourceBergen conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

87. Bellco Drug Corp. (“Bellco”) is a New York Corporation with its principal place of business in Amityville, New York. Bellco is a subsidiary of AmeriSource.

(a) At all times relevant hereto, Defendant Bellco conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

88. Cardinal Health, Inc. (“Cardinal Health”) is an Ohio corporation with its principal office location in Dublin, Ohio. Cardinal Health operates distribution centers in Aurora and Waukegan, Illinois.

(a) At all times relevant hereto, Defendant Cardinal Health conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

89. Kinray, LLC (“Kinray”) is a New York corporation with its principal place of business in Whitestone, New York.

(a) At all times relevant hereto, Defendant Kinray conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

(b) Kinray is a subsidiary of Cardinal Health.

90. McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California. McKesson operates a distribution center in Aurora, Illinois.

(a) At all times relevant hereto, Defendant McKesson conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

91. Together, AmerisourceBergen, Cardinal Health, and McKesson presently collect about 94% of the revenues for prescription drugs distributed in the United States, and during and through the times material herein similarly dominated this area of commerce.

92. Rochester Drug Cooperative, Inc. (“Rochester Drug”) is a New York Corporation with its principal place of business in Rochester, New York.

(a) At all times relevant hereto, Defendant Rochester Drug conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

93. Walgreens Co. is a Delaware Corporation with its principal place of business in Illinois.

(a) At all times relevant hereto, Defendant Walgreens Co. conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

94. Walgreens Boots Alliance, Inc. (“Walgreens Boots”) is a Delaware Corporation with its principal place of business in Illinois. Walgreens Co. and Walgreens Boots are collectively referred to herein as “Walgreens”.

(a) At all times relevant hereto, Defendant Walgreens Boots conducted substantial and continuous business in Pennsylvania, including the sale and distribution of opioid drugs to claimants in Pennsylvania.

95. Defendants AmerisourceBergen, Bellco, Cardinal Health, Kinray, McKesson, Rochester Drug and Walgreens are referred to as the “Distributor Defendants”.

D. Defendants’ Agents and Concerted Activity

96. Defendants, collectively and individually, at all times material herein acted by and through their respective agents, officers, employees, servants and workers, actual, apparent or ostensible, any and all of whom were acting within the course and scope of their actual or apparent duties, employment or authority.

97. Defendants, at all times material herein, acted in concert with each other to cause and produce the harms alleged herein.

FACTUAL BACKGROUND

I. Workers’ Compensation.

98. Plaintiff provided and provides injured workers of its insured employers (these injured workers are referred to herein as “claimants”) with comprehensive workers’ compensation benefits, including the payment of all medical bills associated with treatment of work-related injuries, including prescription drug benefits, income benefits if the injured worker is temporarily or permanently disabled, and death benefits if the injury sustained results in death.

Other members of the Workers' Compensation Payors Class make similar payments.

99. When a claimant is injured on the job, the worker may file a claim for workers' compensation with Plaintiff, or other members of the Class, as applicable.

100. For covered work-related injuries, Plaintiff and members of the Class must pay workers' medical, temporary total disability, and permanent partial disability payments and death benefits where the injury results in death.

101. As to the prescription drugs, doctors and pharmacies submit bills or claims to Plaintiff and members of the Class directly, through Third-Party Administrators or Pharmacy Benefit Managers, who in turn make payment for the costs associated with the prescriptions, including office visits and toxicology screens.

102. Plaintiff and members of the Class paid for prescription opioids prescribed to injured workers to treat non-cancer, chronic pain from work-related injuries, which payments would not have occurred or been necessary but for Defendants' tortious omission, conduct or activities described herein.

103. Plaintiff and members of the Class made disability income and death benefit payments to covered claimants who were prescribed and/or otherwise took prescription opioids Defendants manufactured, marketed, promoted or distributed, which would not have occurred or been necessary but for Defendants' tortious omission, conduct or activities described herein.

104. Plaintiff and members of the Class paid for medical care and treatment (including emergency room and additional treatments) which would not have

occurred or been necessary but for Defendants' tortious omission, conduct or activities described herein.

105. Plaintiff and members of the Class incurred administrative costs as a result of the prescription opioid epidemic which would not have been incurred or been necessary but for Defendants' tortious omission, conduct or activities described herein.

106. Plaintiff and members of the Class thereby sustained ascertainable financial and economic losses proximately caused by Defendants' tortious omission, conduct or activities described herein.

II. Background on pain medicine.

A. Safe and effective treatment of chronic pain centers on informed risk management.

107. The practice of medicine centers on informed risk management: prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment.

108. The safe and effective treatment of chronic pain accordingly requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives, including non-treatment.

109. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients will become physically and psychologically dependent on the drugs, finding it difficult to manage or terminate their use.

110. The FDA-approved drug labels on each of the Manufacturing Defendants' opioids do not attempt to advise physicians on how to maximize the benefits and minimize the risks for patients on long-term chronic opioid therapy.

(a) The labels contain no dosing cap above which it would be unsafe for any doctor to prescribe to any patient.

(b) Nor do any of the labels provide a duration limit, after which the risks to a patient might increase.

(c) Doctors and patients are thus left to rely on educational materials such as treatment guidelines, CMEs, and scientific and patient education articles and websites to inform their treatment decisions, which, as described below and as a part of the Manufacturing and Front Group Defendants' fraudulent marketing scheme, were flooded with inaccurate, false and misleading information.

B. Opioids are highly addictive and offer no proven benefits for the treatment of chronic pain in non-cancer patients.

111. Opioids are a class of drugs that act on the human nervous system by attaching to specific proteins called "opioid receptors." When these receptors are activated by opioids, analgesic effects and a sense of euphoria in the user result. While this response masks pain, it also causes opioids to be highly addictive and to have diminishing efficacy over time, which requires users to resort to higher and higher doses.

112. Common opioids include the drugs morphine, methadone, oxycodone, hydrocodone, codeine, and fentanyl, which are available by prescription, and heroin, which is illegal and only available on the black market.

113. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction and its dangers. Opioids are related to illegal drugs like opium and heroin.

114. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970.

115. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression,” as the result of an excessive dose.

116. With there being few randomized controlled trials regarding opioid efficacy for chronic pain—and indeed, even fewer double-blind studies—the efficacy of long-term opioid use for non-cancer, chronic pain has never been reliably demonstrated.

(a) The first random, placebo-controlled study on the use of opioids for chronic pain was reported in the 1990s. While that study provided evidence for short-term efficacy, it did so only for a minority of patients.¹⁷

(b) Later studies reported similar results. For example, a review of 213 randomized, controlled trials of treatments for cancer pain that was reported in 2004 showed efficacy in the short-term, the data could not substantiate the long-term effectiveness of opioids.

¹⁷ Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Cou, et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

(c) A systematic review of opioid use for back pain likewise reported in 2007 that opioids have limited efficacy for short-term use and that the data did not permit a conclusion on long-term use.

(d) In much the same vein, a systematic review of studies reported in 2011 found that the evidence of long-term efficacy of opioid use for the treatment of non-cancer pain is poor.

(e) A 2006 Canadian meta-analysis found that opioids did not improve functional outcomes over other non-opioid analgesics. To the contrary, the 2006 meta-analysis stated that “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”¹⁸

(f) A Danish study, also reported in 2006, likewise stated that “it is remarkable that opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals: pain relief, improved quality of life, and improved functionality.”¹⁹

(g) The FDA confirmed in a 2013 letter that it was not aware “of [any] adequate and well-controlled studies of opioid use longer than 12-weeks.”²⁰

¹⁸ Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass’n J. 1589 (2006).

¹⁹ Jorgen Eriksen, et al., *Critical Issues on Opioids in Chronic Non-Cancer Pain: An Epidemiological Study*, 125 Pain 172, 176-77 (2006).

²⁰ Letter from Janet Woodcock, M.D., Director, Ctr. For Drug Evaluation & Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), *available at* <http://bit.ly/2F430US> (accessed November 13, 2019).

(h) There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.²¹

117. In contrast to the dearth of evidence in the scientific literature for the long-term efficacy of opioids, there is evidence that opioid users develop a tolerance and therefore require ever greater doses to obtain the same effect.

(a) In a 2002 paper, the authors described how “[r]epeated exposure to escalating dosages of opioids alters the brain so that it functions more or less normally when the drugs are present and abnormally when they are not.”²² That paper continued, also noting that as time goes on, opioid users need higher dose to feel “normal, produce a sense of euphoria comparable to prior doses, and to avoid symptoms of withdrawal.”²³

(b) A patient's tolerance to opioids may even begin after just the first dose.²⁴

²¹ Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

²² Thomas R. Kosten & Rony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. & Practice Perspectives 14 (July 2002).

²³ *Id.*

²⁴ Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconception and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016); Jessica Wapner, *CDC Study Finds Opioid Dependency Begins Within a Few Days of Initial*

118. Endo's research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

119. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

120. As one pain specialist has explained in an article titled, *Are We Making Pain Patients Worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."²⁵

121. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function.

122. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

Use, Newsweek (Mar. 22, 2017), available at <http://www.newsweek.com/cdc-opiate-addiction-572498> (accessed November 13, 2019).

²⁵ Andrea Rubenstein, *Are We Making Pain Patients Worse?*, Sonoma Medicine (Fall 2009).

123. The lack of evidence for the utility of opioid use, especially long-term use for chronic pain, was eventually recognized and well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Studies using workers compensation claim datasets establish that injured workers prescribed even one opioid had average total workers compensation claim costs that are four to eight times greater than claimants with similar claims who did not take opioids and that claims involving workers who take opioids are almost four times as likely to reach costs of over \$ 100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work.²⁶

124. Indeed, as one industry consultant and commentator in a whitepaper published on his firm's website described the growing situation:

Prescription drug abuse is the nation's fastest-growing drug issue, an epidemic affecting all of society and workers' compensation in particular. Prescription opioids are presently the number one workers' compensation problem in terms of controlling the ultimate cost of indemnity losses. There has never been a more damaging impact on the cost of workers' compensation claims from a single issue than the abuse of opioid prescriptions for the management of chronic pain. Nationally, an estimated 55 to 86 percent of all claimants are receiving opioids for chronic pain relief. However, the overwhelming consensus of evidence-based medicine does not support its long-term treatment protocol

²⁶ See Keith E. Rosenblum, *Opioids Wreak Havoc on Workers' Compensation Costs*, Lockton Companies pg. 5 (August 2012) available at https://www.lockton.com/Resource_/PageResource/MKT/wc-pbm-3%20update%208-31.pdf (Accessed Nov. 2, 2019); International Association of Industrial Accident Boards and Commissions, *Reducing Inappropriate Opioid Use in Treatment of Injured Workers: A Policy Guide* (August 28, 2013).

outside of very specific cases, most of which involve end-stage cancer treatment.²⁷

125. Yet, putting profits before public health and patient safety, and realizing that substantial money could be obtained from increasing opioid usage and that there were third-party payors such as Plaintiff who could do little but pay the costs, Defendants devised a scheme to expand the market for opioids beyond cases of acute pain, surgical recovery, cancer treatment, and end-of-life palliative care.

III. To change the then-prevailing perception of opioids, the Manufacturing Defendants promoted their branded opiate products through direct marketing to prescribers and consumers.

126. Before the 1990s, the generally accepted standards of medical practice limited the uses of opioids to only cases of acute pain, surgical recovery, cancer treatment, and end-of-life palliative care. The prevailing view then held that opioids should not be used to treat chronic pain as their efficacy had not been scientifically demonstrated. To the contrary, because patients developed tolerance to opioids over time and the serious risks of addiction and other side effects, there was widespread medical consensus that opioid prescriptions should be limited and controlled.

127. Studies and articles from the 1970s and 1980s made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs: opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to

²⁷ Rosenblum, *Opioids Wreak Havoc on Workers' Compensation Costs*, Lockton Companies, pg. 1.

perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.²⁸

128. According to one researcher from the Harvard Medical School, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids.”²⁹ The Manufacturing and Front Group Defendants changed that perception.

129. The Manufacturing Defendants’ direct marketing proceeded on two tracks, serving two related purposes, hereinafter referred to as the “**Opioid Marketing Enterprise.**”

(a) First, these Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating the benefits of long-term opioid use and downplaying its risks, thereby creating and expanding the chronic pain market.

(b) Second, the Manufacturing Defendants worked through their own staffs of sales representatives, physician speakers whom those representatives recruited, and advertising in medical journals to claim their share of this broader

²⁸ Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986) (“[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”)

²⁹ Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012).

market. These Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

A. The Manufacturing Defendants employed branded advertisements to develop and increase the market for prescription opiate drugs.

130. The Manufacturing Defendants engaged in widespread advertising campaigns touting the benefits of their branded opioid drugs.

131. The Manufacturing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*.

132. The Manufacturing Defendants' advertising budgets peaked in 2011, when they collectively spent more than \$14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

133. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain.

134. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional

improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

B. The Manufacturing Defendants employed their sales forces and recruited physician speakers to develop and increase the market for prescription opiate drugs.

135. Each Manufacturing Defendant promoted the use of opioids for chronic pain through “detailers”— sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs.

136. By establishing close relationships with doctors, the Manufacturing Defendants’ sales representatives were able to disseminate their misrepresentations in targeted, structured one-on-one settings that allowed them to differentiate their opioid products and to address individual prescribers’ concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships.

137. The Manufacturing Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits.

138. In accordance with common industry practice, the Manufacturing Defendants purchased and closely analyzed prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

139. In particular, the Manufacturing Defendants relied upon “influence mapping”—*i.e.*, using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact.

140. Endo, for example, identified prescribers representing 30% of its nationwide sales volume and planned to visit these physicians three times per month.

141. The Manufacturing Defendants also closely monitored doctors’ prescribing after a sales representative’s visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

142. The Manufacturing Defendants’ sales representatives eventually visited hundreds of thousands of doctors that prescribed opioid pain medications paid for by Plaintiff and the Workers’ Compensation Payors, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks and benefits of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses.

143. Each Manufacturing Defendant carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company’s drugs specifically, and opioids in general.

144. The Manufacturing Defendants exactingly directed and monitored their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers

actually delivered the desired messages and do not veer off-script. Pharmaceutical companies likewise required their detailers to deploy sales aids commissioned, reviewed, approved, and supplied by the company and forbade them to use, in industry parlance, “homemade bread”—*i.e.*, promotional materials not approved by the company’s marketing and compliance departments. Sales representatives’ adherence to their corporate training is typically included in their work agreements. Departing from their company’s approved messaging could lead to severe consequences including termination of employment.

145. Besides carefully training their sales representatives, the Manufacturing Defendants used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers.

146. In addition to making sales calls, the Manufacturing Defendants’ detailers also identified doctors to serve, for payment, on their speakers’ bureaus and/or to attend programs with speakers and meals paid for by the Manufacturing Defendants. the Manufacturing Defendants almost always selected physicians who were “product loyalists,” as they were sure to be asked whether they prescribe the drug themselves.

147. Endo, for instance, sought to use specialists in pain medicine—including high prescribers of its drugs—as local “thought leaders” to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for these bureaus with honorarium rates ranging from \$800 to \$2,000 per program,

depending on the type of event, and speaker training typically compensated at \$500 per hour.

148. These speaker programs and associated speaker trainings served three purposes: (a) they provided an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; (b) they provided a medium in which to further market to the speaker him or herself; and (c) they provided an opportunity to market to the speaker's peers.

149. The Manufacturing Defendants graded their speakers and future opportunities were based on speaking performance, post-program sales, and product usage. The Manufacturing Defendants also tracked the prescribing of the events' attendees, with Endo noting that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before." It would make little sense for these defendants to devote significant resources to programs that they did if they did not increase their sales.

150. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them.

151. Endo's speaker rules, for example, provide that "all slides must be presented in their entirety and without alterations . . . and in sequence." This is important because the FDA regards promotional talks as part of product labeling and requires their submission for review.

152. Speakers gave the appearance of providing independent, unbiased presentations on opioids, when, in fact, they were presenting a script prepared by the Manufacturing Defendants' marketing departments. Although these meal-based speaker events are more expensive to host, and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afforded the Manufacturing Defendants greater freedom in the messages they present.

153. The Manufacturing Defendants devoted massive resources to these direct sales contacts with prescribers.

154. In 2014, the Manufacturing Defendants collectively spent \$168 million on detailing branded opioids to physicians nationwide. This figure includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Actavis. The total figure is more than double the Manufacturing Defendants' collective spending on detailing in 2000.

155. The detailers' role in the Manufacturing Defendants' overall promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

156. The Manufacturing Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate

that marketing can and does impact doctors' prescribing habits,³⁰ and face-to-face detailing has the highest influence on intent to prescribe. The Manufacturing Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers whom they targeted for detailing, and who responded by prescribing more of the Manufacturing Defendants' drugs.

C. The Manufacturing Defendants directed these promotional efforts through detailed marketing plans.

157. The Manufacturing Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Defendants' opioids.

i. Targeting categories of prescribers.

158. The Manufacturing Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing.

³⁰ See, e.g., Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

159. The Manufacturing Defendants chose their targets based on the potential for persuading a provider to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses, with no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

160. Collectively, the Manufacturing Defendants' marketing plans evinced dual strategies, which often operated parallel to one another.

(a) The Manufacturing Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists, the highest-volume prescribers of opioids and, as a group, more educated than other practitioners about opioids' risks and benefits.

(b) Seeking to develop market share and expand sales, however, the Manufacturing Defendants also targeted increasing numbers and types of other prescribers for marketing.

161. This expanded market of prescribers was, as a group, less informed about opioids and, as the Manufacturing Defendants' market research concluded, more susceptible to the Manufacturing Defendants' marketing messages. These prescribers included nurse practitioners and physician assistants who, a 2012 Endo business plan noted, were "share acquisition" opportunities because they were "3x times more responsive than MDs to details" and wrote "96% of [their] prescriptions . . . without physician consult."

162. The expanded prescribers market also included internists and general practitioners who were low- to mid-volume prescribers.

163. Actavis, for example, rolled out a plan in 2008 to move beyond “Kadian loyalists” to an “expanded audience” of “low morphine writers.”

ii. Increased “direct to consumer” marketing to develop and increase the market for prescription opiate drugs.

164. The Manufacturing Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications.

165. Endo’s research, for example, found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations.

166. The Manufacturing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician’s office, as well as employer and workers’ compensation plan initiatives to, as Endo put it, “[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss.”

167. The Manufacturing Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor’s drug—was out-of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Manufacturing Defendants did so through vouchers and coupons distributed during detailing visits with prescribers.

168. A 2008 Actavis business review, for example, highlighted co-pay assistance, good for up to \$600 per patient per year, as a way to drive conversions to Kadian from competitor drugs like Avinza and MS Contin. In 2012, Janssen planned to distribute 1.5 million savings cards worth \$25 each.

iii. Differentiating each brand.

169. By 2010, Defendants had begun facing increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse.

170. Market conditions prompted the Manufacturing Defendants to pursue product differentiation strategies—particularly an emphasis on their products being less subject to diversion, abuse, and addiction—as a means of grabbing market share from Purdue and other competitors.

171. Endo, for example, tracked in detail prescriber “switching” from OxyContin to Opana ER. Actavis and Janssen did the same for switches to Kadian and Nucynta ER, respectively.

172. Pressure to stand out among other drugs resulted in Manufacturing Defendants identifying marketing themes that thereafter were reflected in Defendants’ deceptive and harmful messages to physicians and consumers.

173. A 2008 Janssen plan emphasized “value” messaging in support of Nucynta ER, including claims of less dose escalation, lower toxicity, fewer withdrawal symptoms, and less dependence, and a 2009 Opana ER market research

report focused on greater potency and lower abuse potential of Opana ER vis-à-vis OxyContin.

iv. Moving beyond office visits.

174. The Manufacturing Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so-called “e-detailing.”

175. The Manufacturing Defendants also created new platforms for their speakers by implementing “peer to peer” programs such as teleconferences and webinars that were available to prescribers nationally.

176. These programs allowed the Manufacturing Defendants to use this seemingly more credible vehicle to market to, among other hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person detailing.

177. Employing these new approaches, each Defendant relied heavily on speakers to promote its drugs.

D. The Manufacturing Defendants marketed opioids using the same strategies and messages they employed nationwide.

178. The Manufacturing Defendants employed the same marketing plans and strategies and deployed the same messages to prescribers that wrote opioid prescriptions for the claimants of Plaintiff and other Workers’ Compensation Payors, and which were paid for by Plaintiff and the other Workers’ Compensation Payors.

179. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by corporate headquarters.

180. This comprehensive approach ensures that the Manufacturing Defendants’ messages were accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory.

181. The Manufacturing Defendants considered this high level of coordination and uniformity crucial to successfully marketing their drugs.

182. The Manufacturing Defendants ensured marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturing Defendants’ sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors traveled with them periodically to check on both their performance and compliance.

183. As they did nationwide, the Manufacturing Defendants extensively tracked the prescribing behavior of health care providers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors and used that data to target their detailing and speaker recruiting efforts. Top prescribers were profiled at the city, region, zip code, and sometimes facility levels, with

information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

184. Misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of the Manufacturing Defendants' marketing campaigns.

IV. The Manufacturing Defendants used "unbranded" marketing to evade regulations and consumer protection laws.

185. In addition to their direct marketing efforts, the Manufacturing Defendants used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs.

186. Each Manufacturing Defendant executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts.

187. The Manufacturing Defendants exercised substantial control over the content of the messages third parties generated, disseminated, and distributed certain of those materials themselves.

188. As with their other marketing strategies, the Manufacturing Defendants' unbranded marketing created, and relied upon, an appearance of independence and credibility that was undeserved but central to its effectiveness.

189. Unlike their direct promotional activities, the Manufacturing Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

A. Regulations governing branded promotion require that it be truthful, balanced, and supported by substantial evidence.

190. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs.

191. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.³¹

192. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

193. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular" way.³² "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."³³ "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug,

³¹ 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

³² 21 U.S.C. §§ 352.

³³ 21 C.F.R. § 201.5.

including promotional material.³⁴ “The term “accompanying” is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.³⁵ Thus, the Manufacturing Defendants’ promotional materials are part of their drugs’ labels and are required to be accurate, balanced, and not misleading.

194. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product’s risks. “The most serious risks set forth in a product’s labeling are generally material to any presentation of efficacy.” The FDA notes that “[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included.”³⁶ Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

195. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug’s safety or efficacy or present conclusions that “clearly cannot be supported by the results of the study.”³⁷ Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that “a drug is safer or more effective than another drug

³⁴ 21 U.S.C. § 321(m).

³⁵ *See id.*

³⁶ FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.

³⁷ 21 C.F.R. § 99.101(a)(4).

in some particular way when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.”³⁸

196. While the FDA must approve a drug’s label, it is the drug company’s responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.³⁹ Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or a warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

B. Defendants deployed front groups and doctors to disseminate unbranded information on their behalf.

197. Drug companies market both directly and indirectly, using third-party validators (such as scientists, physicians, patient or professional organizations) that

³⁸ 21 C.F.R. § 202.1(e)(6)(ii).

³⁹ See 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that “strengthen . . . a warning, precaution, or adverse reaction” or “strengthen a statement about drug abuse, dependence, psychological effect, or overdose”).

appear to be independent and therefore more credible. The FDA has made clear that its promotional requirements apply to both forms of marketing:

FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.

. . .

Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (*e.g.*, a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.⁴⁰

198. In addition to being carried out directly or through third parties, drug companies' promotional activities can be branded or unbranded.

199. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework governing branded communications.

200. The Manufacturing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials.

⁴⁰ FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, January 2014, at 1, 4, <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf> (accessed November 18, 2019).

201. These KOLs and Front Groups were important elements of the Manufacturing Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and thus outside FDA oversight.

202. Through unbranded materials, the Manufacturing and Front Group Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on the Manufacturing Defendants' branded marketing materials and drug labels.

203. The Manufacturing Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

204. Even where such unbranded messages were channeled through third-party vehicles, the Manufacturing Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete.

205. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. See 21. C.F.R. 202.1(e)(7)(l)(2).⁴¹

⁴¹ This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-

206. The Manufacturing Defendants’ sales representatives distributed third-party marketing material that was deceptive to Defendants’ target audiences. Defendants are responsible for these materials.

207. Moreover, the Manufacturing Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Defendants were consistently aware of their content.

208. By funding, directing, editing, and distributing these materials, the Manufacturing Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.⁴²

209. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials if there is no evidence for such claims. Thus, drug companies were put on notice that the FDA does not allow such claims in branded materials. The Manufacturing and Front Group Defendants instead created and disseminated these same unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through unbranded marketing materials.

created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

⁴² As used in this Complaint, the allegation that Defendants “acted in concert” with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

210. The third-party publications Manufacturing and Front Group Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

211. By acting through third-parties, the Manufacturing Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, the Manufacturing Defendants would cite to these sources as “independent” corroboration of their own statements. As one physician adviser to Defendants noted, third-party documents not only had greater credibility, but broader distribution as doctors did not “push back” at having materials from, for example, the non-profit American Pain Foundation (“APF”) on display in their offices, as they might with first-party, drug company pieces. Nevertheless, the independence of these materials was a ruse— the Manufacturing Defendants were in close contact with these third parties, paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

212. As part of a strategic marketing scheme, the Manufacturing Defendants spread and validated their deceptive messages through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles

and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

i. The Manufacturing Defendants' use of KOLs.

213. The Manufacturing and Front Group Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids.

214. The Manufacturing and Front Group Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

215. Pro-opioid doctors have been at the hub of the Manufacturing and Front Group Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain.

216. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy

groups and professional societies that develop, select, and present CMEs. The Manufacturing and Front Group Defendants were able to exert control of each of these modalities through their KOLs.

217. In return, the KOLs' association with the Manufacturing and Front Group Defendants provided them not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

218. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, the Manufacturing and Front Group Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market.

219. The Manufacturing and Front Group Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain. These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

220. The Manufacturing and Front Group Defendants cited and promoted favorable studies or articles by these KOLs.

221. By contrast, the Manufacturing and Front Group Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy.

222. Indeed, one prominent KOL sponsored by the Manufacturing and Front Group Defendants, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

223. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

224. The Manufacturing Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

225. The Manufacturing Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than \$4.5 million for programs relating to its opioids.

226. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

227. The Manufacturing Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also

scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to Plaintiff and the Workers’ Compensation Payors.

a. Russel Portenoy

228. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturing Defendants identified and promoted to further their marketing campaign.

229. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

230. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of APF, an advocacy organization almost entirely funded by Defendants.

231. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched

program, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”⁴³

232. Portenoy has recently admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids.

233. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”⁴⁴ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”⁴⁵

b. Lynn Webster

234. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member

⁴³ Good Morning America television broadcast, ABC News (Aug. 30, 2010).

⁴⁴ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.

⁴⁵ *Id.*

of AAPM, a front group that ardently supports chronic opioid therapy.⁴⁶ He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturing Defendants (including nearly \$2 million from Cephalon).

235. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths."

⁴⁶ Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

This webinar was available to and was intended to reach doctors that wrote opioid prescriptions for Plaintiff and the Workers' Compensation Payors.

236. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to *increase* a patient’s dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁴⁷

ii. “Research” that lacked supporting evidence.

237. Rather than find a way to validly test the safety and efficacy of opioids for long-term use, the Manufacturing and Front Group Defendants led people to believe that they already had.

238. The Manufacturing and Front Group Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b)

⁴⁷ John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012).

appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors.

239. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

240. To accomplish this, the Manufacturing and Front Group Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants’ internal documents reveal plans to submit research papers and “studies” to long lists of journals, including back-up options and last resort, “fast-track” application journals, that they could use if the pending paper was rejected everywhere else.

241. The Manufacturing and Front Group Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs.

(a) The plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in the Manufacturing Defendants’ marketing departments and with Defendants’ marketing and public relations consultants.

(b) The Manufacturing and Front Defendants often relied on “data on file” or presented posters, neither of which are subject to peer review.

(c) They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

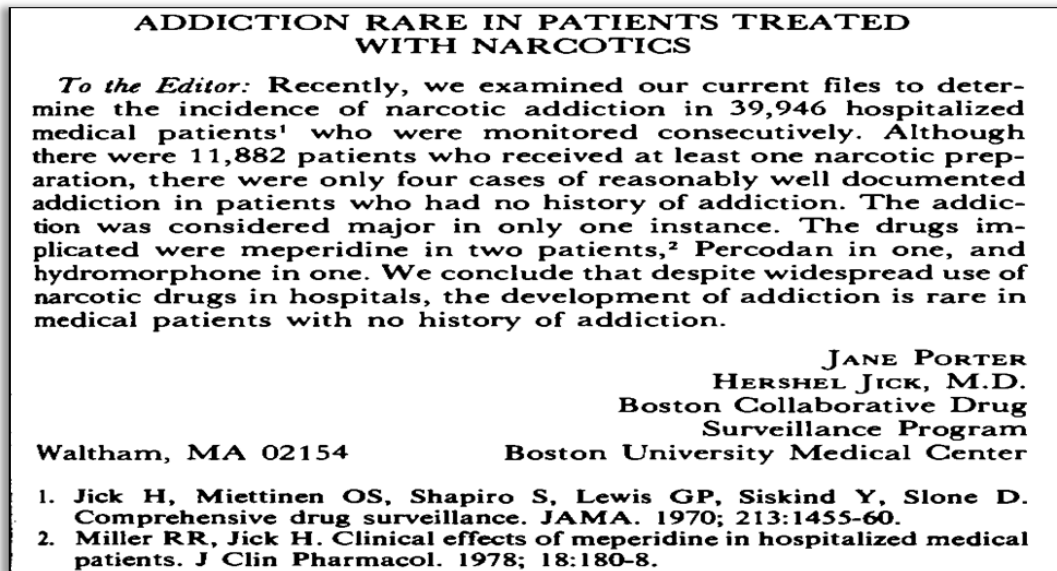
242. The Manufacturing and Front Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study.

243. For example, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) (“Porter-Jick Letter”), which has been cited frequently in articles appearing on Google Scholar. It also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.⁴⁸ Defendants, and those acting on their behalf, fail to reveal that this “article” is actually a letter-to-the-editor and not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980

⁴⁸ AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; “Chronic Pain Management and Opioid Use,” October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers that wrote opioid prescriptions for Plaintiff and the Workers’ Compensation Payors.

study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

244. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.



245. The Manufacturing and Front Group Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. The Manufacturing and Front Group Defendants' studies and articles often targeted articles that contradicted the Manufacturing Defendants' claims or

raised concerns about chronic opioid therapy. In order to do so, the Manufacturing Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

246. The Manufacturing and Front Group Defendants’ strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are in dereliction of their legal obligations.

247. The Manufacturing and Front Group Defendants’ strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

iii. Treatment Guidelines.

248. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors (including Workers’ Compensation Payors) in determining whether they should cover treatments for specific indications. Furthermore, Endo’s internal documents

indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

a. Federation of State Medical Boards

249. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

250. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“FSMB Guidelines”), which FSMB admitted was produced “in collaboration with pharmaceutical companies.” The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that “inadequate understandings” of addiction can lead to “inadequate pain control.”

251. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach physicians that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors for their claimants.

252. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

253. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately \$250,000 in revenue and commissions from their sale. The FSMB website describes the book as the “leading continuing medication education (CME) activity for prescribers of opioid medications.”

254. Drug companies relied on FSMB guidelines to convey the message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

255. FSMB, subsequently moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that “pseudoaddiction” is real and that opioid addiction risk can be managed through risk screening, it no longer

recommended chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

b. AAPM/APS Guidelines

256. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over \$2 million).

257. The AAPM and the APS issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁴⁹ The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011.

258. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines" or "Consensus Recommendation") and continued to recommend the use of opioids to treat chronic pain.⁵⁰ Fourteen of the 21 panel members who drafted the AAPM/APS

⁴⁹ Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <https://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (accessed November 2, 2019).

⁵⁰ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) *The J. of Pain: Official J. of the Am. Pain Soc'y* 113-130 (2009).

Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

259. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.

260. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines went on to be cited often in academic literature, were widely disseminated during the relevant time period, are still available online⁵¹, and were reprinted in the *Journal of Pain*.

261. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

c. American Geriatrics Society

262. The American Geriatrics Society (“AGS”), a nonprofit organization serving health care professionals who work with the elderly, disseminated

⁵¹ See e.g., <https://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (accessed November 2, 2019).

guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter “2009 AGS Guidelines”).

263. The 2009 AGS Guidelines included the following recommendations: “All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation),” and “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”⁵² These recommendations, which continue to appear on AGS’s website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited numerous times in Google Scholar since their 2009 publication.

264. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants including Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to

⁵² *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), *available at* <http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full> (accessed November 13, 2019).

disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies.

265. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

266. According to one news report, AGS has received \$344,000 in funding from opioid makers since 2009.⁵³ Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock.

267. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

c. Guidelines that did not receive Defendants' support.

268. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions.

269. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians

⁵³ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel (May 30, 2012).

(“ASIPP”), warned that “[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects.”⁵⁴

270. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits

⁵⁴ Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

based on limited evidence,” while conceding there may be patients for whom opioid therapy is appropriate.⁵⁵

271. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, noted that their review:

revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . . ; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . . ; lack of evidence on the utility of informed consent and opioid management plans . . . ; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.⁵⁶

iv. Continuing medical education.

272. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered

⁵⁵ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids*, (2011), available at: <https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf> (accessed February 18, 2019).

⁵⁶ Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010).

by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

273. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

274. In all, Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

275. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."⁵⁷

⁵⁷ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

276. Dozens of CMEs that were available to and attended or reviewed by doctors that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors during the relevant time period did not live up to the AMA's standards.

277. The influence of Defendants' funding on the content of these CMEs is clear.

278. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CMEs mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.⁵⁸

⁵⁸ Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010).

279. By sponsoring CME programs presented by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects.

280. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

v. Unbranded patient education.

281. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in “increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats.”⁵⁹

282. Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug—even for opioids and for conditions for which they are not generally recommended.⁶⁰

⁵⁹ Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

⁶⁰ Prescribers often accede to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

283. An Actavis marketing plan, for example, noted that “[d]irect-to-consumer marketing affects prescribing decisions.”

284. The Manufacturing Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

285. The drug companies expected and continue to expect that they will recoup their investment in direct-to-consumer advertisements by capturing at least some of any additional prescriptions that result from patients “asking their doctor” about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

vi. The Manufacturing Defendants’ use of front groups.

286. As noted above, Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon the Manufacturing Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting the Manufacturing Defendants’ marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by the Manufacturing Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on the use of opioids to

treat chronic pain. The Manufacturing Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

287. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association (“ACPA”), AAPM, American Society of Pain Educators (“ASPE”), NPF, and PPSG.

a. American Pain Foundation

288. The most prominent of the Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half of that funding; Purdue was next, at \$1.7 million.

289. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and other Workers’ Compensation Payors.

290. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

291. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

292. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for the Manufacturing Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of the Manufacturing Defendants, not patients.

293. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings

at Front Group conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

294. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter’s Guide: Covering Pain and Its Management* (2008)⁶¹—recycled text that was originally created as part of the company’s training document.

295. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, “I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?”

296. The close relationship between APF and the drug company was not unique, but in fact mirrors the relationships between APF and the Manufacturing Defendants. APF’s clear lack of independence—in its finances, management, and mission—and its willingness to allow the Manufacturing Defendants to control its activities and messages, support an inference that each Defendant that worked with APF was able to exercise editorial control over its publications.

⁶¹ <https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf> (accessed February 18, 2019).

297. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers.

298. The Finance Committee's investigation caused considerable damage to APF's credibility as an objective and neutral third party and the Manufacturing Defendants stopped funding it.

299. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."⁶²

b. The American Academy of Pain Medicine

300. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of the Manufacturing Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

301. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay \$25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

⁶² <http://www.painfoundation.org> (last visited May 30, 2017).

302. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings.

303. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

304. AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members.

305. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

306. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”⁶³

307. AAPM’s staff understood that they and their industry funders were engaged in a common practice.

⁶³ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005).

308. The Manufacturing Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

C. The Manufacturing Defendants acted in concert with KOLs and Front Groups in the creation, promotions, and control of unbranded marketing.

309. Like cigarette manufacturers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, the Manufacturing Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

310. The Manufacturing Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with the Manufacturing Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to prescribers and the claimants of Plaintiff and the Workers' Compensation Payors.

(a) Pain Care Forum

311. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and

support taking collaborative action regarding federal pain policy issues.” APF President Will Rowe described the Forum as “a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations.”

312. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from the Manufacturing Defendants.

313. PCF, for example, developed and disseminated “consensus recommendations” for a Risk Evaluation and Mitigation Strategy (“REMS”) for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁶⁴ This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate the Manufacturing Defendants’ marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were “essential” to the management of pain, and that the REMS “should acknowledge the importance of opioids in the management of pain and should not introduce new

⁶⁴ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

barriers.”⁶⁵ The Manufacturing Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

V. Why Defendants’ marketing is misleading and unfair.

314. The marketing of opioids for long-term use to treat chronic pain, both directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids while overstating their benefits. Defendants moreover inaccurately suggested that chronic opioid therapy was supported by evidence and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

315. There are seven primary misleading and unfounded representations Defendants and the third parties with which they teamed made:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them “pseudoaddiction”;
- falsely claimed withdrawal is easily managed;

⁶⁵ Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

316. In addition to these misstatements, Purdue purveyed an eighth deception that OxyContin provides a full 12 hours of pain relief.

317. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community the fact that the FDA “is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks.”⁶⁶

A. Regulations governing branded promotion require that it be truthful, balanced, and supported by substantial evidence.

318. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients’ function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing dosage or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

⁶⁶ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

319. Not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that “[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids.”⁶⁷ Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients’ function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity.⁶⁸ Indeed, one of Defendant’s own internal marketing plans characterized functional improvement claims as “aspirational.” Another acknowledged in 2012 that “[s]ignificant investment in clinical data [was] needed” to establish opioids’ effect on mitigating quality of life issues, like social isolation.

320. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients’ ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

⁶⁷ Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass’n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

⁶⁸ Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

321. Yet each of the following statements made by Defendants suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim.

Actavis

- a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy." (Emphasis added.)
- b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function.
- c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁶⁹
- d. Actavis sales representatives told prescribers who wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life.

⁶⁹ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm>.

Cephalon

- e. Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent \$150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.
- f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options Guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report.
- g. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, titled Optimizing Opioid Treatment for Breakthrough Pain, which was offered online by Medscape, LLC from September 28, 2007, to December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long- acting opioids.
- h. Cephalon sales representatives told prescribers that wrote opioid prescriptions paid for the Workers' Compensation Payors that opioids would increase patients' ability to function and improve their quality of life.

Endo

- i. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.
- j. A CME sponsored by Endo, titled Persistent Pain in the Older Patient, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning. A CME sponsored by Endo, titled Persistent Pain in the Older Patient, taught that chronic opioid therapy has

been “shown to reduce pain and improve depressive symptoms and cognitive functioning

- k. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER’s indication without including equally prominent disclosure of the “moderate to severe pain” qualification.⁷⁰
 - l. Endo’s sales force distributed FSMB’s Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients’ function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a “long-term therapeutic treatment course.”
 - m. Endo provided grants to APF to distribute Exit Wounds to veterans, which taught that opioid medications “increase your level of functioning” (emphasis in the original). Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.
 - n. Endo sales representatives told prescribers who wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that opioids would increase patients’ ability to function and improve their quality of life by helping them become more physically active and return to work.
- Janssen**
- o. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a “fact” that “opioids may make it easier for people to live normally” (emphasis in the original). The myth/fact structure implies authoritative backing for the claims that

⁷⁰ FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes “misbranding” of the product. 21 C.F.R. § 202.1(e)(3); *see also* 21 U.S.C. § 331(a).

does not exist. The targeting of older adults also ignored heightened opioid risks in this population

- p. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in Let's Talk Pain Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative.
- q. Janssen provided grants to APF to distribute Exit Wounds to veterans, which taught that opioid medications "increase your level of functioning" (emphasis in the original). Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.
- r. Janssen sales representatives told prescribers of workers' compensation payors that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

Purdue

- s. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "*Pain vignettes*," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.
- t. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."

- u. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report.
- v. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.
- w. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over \$ 100,000 to support distribution of the book.
- x. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that opioids would increase patients' ability to function and improve their quality of life.

B. Defendants and their third-party allies concealed the truth about the risk of addiction from long-term opioid use.

322. The fraudulent representation that opioids are rarely addictive is central to the Manufacturing Defendants' scheme. To reach chronic pain patients, Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate concerns and fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk—condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for the Manufacturing Defendants' campaign to

convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have, and previously had, posed a nearly insurmountable challenge.

323. Through their well-funded, comprehensive marketing efforts, the Manufacturing Defendants and their KOLs and Front Groups were able to change prescriber perceptions despite the well-settled historical understanding and clear evidence that opioids taken long-term are often addictive. Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (b) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and the Manufacturing Defendants’ own labels—compelled disclosure.

324. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addiction altogether, the Manufacturing and Front Group Defendants employed language that conveyed to prescribers that the drugs had lower potential for abuse and addiction. Further, in addition to making outright misrepresentations about the risk of addiction, or failing to disclose that serious risk at all, these defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction. For instance, sales representatives for Actavis, Endo, Janssen, and Purdue promoted their drugs as having “steady-state” properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can

trigger abuse and addiction. Further, Endo actively promoted its reformulated Opana ER on the basis that it was “designed to be crush-resistant,” suggesting both (a) that Endo had succeeded in making the drug harder to adulterate, and (b) that it was less addictive, in consequence. In fact, however, Endo knew that “the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER” and that Opana ER could still be ground and cut into small pieces by those looking to abuse the drug. In the same vein, Janssen denied that Nucynta ER was an opioid and claimed that it was not addictive, and Purdue claimed that its opioids were not favored by addicts and did not produce a buzz, all of which falsely suggested that its opioids were less likely to be abused or addictive.

325. Each of the following was created with the expectation that, by instructing patients and prescribers that addiction rates are low and that addiction is unlikely when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue—APF’s 2011 *A Policymaker’s Guide to Understanding Pain & Its Management*—claimed that opioids are not prescribed often enough because of “misconceptions about opioid addiction.”⁷¹

326. Acting directly or with and through third parties, each of the Manufacturing Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence

⁷¹ <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (accessed November 18, 2019).

to support those claims, and the available research contradicted them. A 2015 literature survey found that while ranges of “problematic use” of opioids ranged from <1% to 81%,⁷² abuse averages ranged between 21% and 29% and addiction averages between 8% and 12%.⁷³ These estimates are well in line with Purdue’s own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, instead citing the Porter-Jick letter.

327. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential “red flags” for abuse or addiction.⁷⁴ The FDA, in fact, has ordered manufacturers of long-acting opioids to “[c]onduct one or more studies to provide *quantitative estimates* of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain,” in recognition of the fact that it found “high rates of addiction” in the medical literature.⁷⁵

⁷² Kevin Vowels et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015). Cited as basis for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine*.

⁷³ *Ibid.*

⁷⁴ Len Paulozzi, M.D., “Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse.”

⁷⁵ September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, *available at* <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf> (accessed November 13, 2019).; Letter from Janet Woodcock, M.D., Dir., Ctr.

328. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids is also powerful evidence that Defendants' statements regarding the low risk of addiction were, and are, untrue. This was well-known to Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

329. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. Examples of these misrepresentations are laid out below:

Actavis

- a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction.
- b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is possible, but it is "less likely if you have never had an addiction problem." Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry.
- c. Kadian sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused.

for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

- d. Kadian sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids.
- e. Kadian sales representatives omitted any discussion of addiction risks related to Actavis's drugs to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

Cephalon

- f. Cephalon sponsored and facilitated the development of a guidebook, Opioid Medications and REMS: A Patient's Guide, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."
- g. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
- h. Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs to prescribers that wrote opioid prescriptions paid for by the Workers' Compensation Payors.

Endo

- i. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence.
- j. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was designed to be crush resistant, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse.
- k. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a concern.

The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

- l. Endo sponsored a website, PainAction.com, which stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”
- m. Endo sponsored CMEs published by APF’s NIPC, of which Endo was the sole funder, titled Persistent Pain in the Older Adult and Persistent Pain in the Older Patient. These CMEs claimed that opioids used by elderly patients present “possibly less potential for abuse than in younger patients[,]” which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.
- n. Endo distributed an education pamphlet with the Endo logo titled Living with Someone with Chronic Pain, which inaccurately minimized the risk of addiction: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- o. Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy titled Understanding Your Pain: Taking Oral Opioid Analgesics. It claimed that “[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems.” This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue.
- p. Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the Pharmacological Management of Persistent Pain in Older Persons. These guidelines falsely claim that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines’ content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.
- q. Endo sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that its drugs were “steady state,” the implications of which was that they did not produce a rush or

euphoric effect, and therefore were less addictive and less likely to be abused.

r. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.” Although the term “very unlikely” is not defined, the overall presentation suggests that the risk is so low as not to be a concern.

s. Endo sales representatives omitted discussion of addiction risks related to Endo’s drugs.

Janssen

t. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a “myth” that opioids are addictive, and asserts as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.” Although the term “rarely” is not defined, the overall presentation suggests the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem.

u. Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines’ content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

v. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.” Although the term “very unlikely” is not defined, the overall presentation suggests the risk is so low as not to be a concern.

- w. Janssen currently runs a website, *Prescriberesponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are “overstated.”
- x. A June 2009 Nucynta Training module warns Janssen’s sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because “the risks . . . are much smaller than commonly believed.”
- y. Janssen sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.
- z. Janssen sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that Nucynta and Nucynta ER were “not opioids,” implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen’s drugs. In truth, however, as set out in Nucynta’s FDA-mandated label, Nucynta “contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit.”
- aa. Janssen sales representatives falsely told prescribers that Duragesic had anti abuse properties when it had none.
- bb. Janssen’s sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that Nucynta’s unique properties eliminated the risk of addiction associated with the drug.
- cc. Janssen sales representatives omitted discussion of addiction risks related to Janssen’s drugs.
- Purdue** dd. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, “Indications of Possible Drug Abuse,” shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.⁷⁶ Thus, these

⁷⁶ Purdue itself submitted briefing materials in October 2010 to a meeting of the FDA’s Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee

misrepresentations wrongly reassure doctors that, as long as they do not observe those signs, they need not be concerned that their patients are abusing or addicted to opioids.

- ee. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction."
- ff. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
- gg. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."⁷⁷ The study relied only on the Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a concern.
- hh. Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.
- ii. Purdue sponsored APF's *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the

and the Drug Safety and Risk Management Advisory Committee in which it stated that OxyContin was used non-medically by injection 4-17% of the time.

⁷⁷ C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial* *1* *painful diabetic neuropathy*, 105 *Pain* 71 (2003).

term “very unlikely” is not defined, the overall presentation suggests it is so low as not to be a worry.

jj. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

kk. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that Butrans has a lower abuse potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a “buzz” from increased dosage.

ll. Advertisements that Purdue sent to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction.

mm. Purdue sales representatives omitted discussion of addiction risk related to Purdue’s drugs.

330. In addition to denying or minimizing the risk of addiction and abuse generally, the Manufacturing Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors’ or predecessor drugs. In making these claims, the Manufacturing Defendants said or implied that because their drug had a “steady-state” and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting. Endo also asserted in particular that, because a reformulation of Opana ER was (or was designed to be) abuse-deterrent or tamper-resistant, patients were less likely to become addicted to it. The Manufacturing Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head

trials;⁷⁸ the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

331. Further, rather than honestly disclose the risk of addiction, the Manufacturing Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, The Manufacturing and Front Group Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). The Manufacturing Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

332. For example, Janssen's website, *Let's Talk Pain*, warns in a video posted online that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare

⁷⁸ See *Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

professionals have been reluctant to prescribe opioids for their patients This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States.”

333. In the same vein, a Purdue website called *In the Face of Pain* complains, under the heading of “Protecting Access,” that, through at least mid-2013, policy governing the prescribing of opioids was “at odds with” best medical practices by “unduly restricting the amounts that can be prescribed and dispensed”; “restricting access to patients with pain who also have a history of substance abuse”; and “requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe.” This unsupported and untrue rhetoric aims to portray doctors who do not prescribe opioids as uncaring, converting their desire to relieve patients’ suffering into a mandate to prescribe opioids.

C. Defendants and their third-party allies misrepresented that addiction risk can be avoided and managed.

334. To this day, Defendants each continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain why doctors encounter so many patients addicted to opioids, Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance

abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

335. There are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

336. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. A 2014 Evidence Report by the Agency for Healthcare Research and Quality (“AHRQ”), which “systematically review[ed] the current evidence on long-term opioid therapy for chronic pain” identified “[n]o study” that had “evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse- deterrent formulations on outcomes related to overdose, addiction, abuse or misuse.”⁷⁹ Furthermore, attempts to treat high-risk patients, such as those who have a documented predisposition to substance abuse, by resorting to patient contracts,

⁷⁹ *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).

more frequent refills, or urine drug screening are not proven to work in the real world, if busy doctors even in fact attempt them.

337. Most disturbingly, despite the widespread use of screening tools, patients with past substance use disorders—which every tool rates as a risk factor—receive, on average, higher doses of opioids.

338. Each Defendant claimed that the risk of addiction could be avoided or managed, claims that are deceptive and without scientific support:

- | | |
|-----------------|---|
| Actavis | a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction. |
| Cephalon | b. Cephalon sponsored APF's <i>Treatment Options: A Guide for People Living with Pain</i> (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed." |
| Endo | c. Endo paid for a 2007 supplement ⁸⁰ available for continuing education credit in the <i>Journal of Family Practice</i> . This publication, titled <i>Pain Management Dilemmas in Primary Care: Use of Opioids</i> , recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. |
| Purdue | d. Purdue's unbranded website, <i>In the Face of Pain</i> (inthefaceofpain.com) states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices. ⁸¹ |

⁸⁰ The Medical Journal, *The Lancet*, found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing," 375 *The Lancet* 9712 (347) 2010.

⁸¹ See *In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment*, Purdue Pharma L.P.

- e. Purdue sponsored a 2012 CME program taught by a KOL titled Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.
- f. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled Managing Patient's Opioid Use: Balancing the Need and Risk. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."
- g. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

D. Defendants and their third-party allies created confusion by promoting the misleading term "pseudoaddiction."

339. Defendants and their third-party allies developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are actually the product of untreated pain, doctors would prescribe opioids to more patients and continue to prescribing them, and patients would continue to use opioids despite signs that the patient was addicted.

340. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both.

As KOL Dr. Lynn Webster wrote: “[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept.”⁸²

341. Each of the publications and statements below falsely states or suggests that the concept of “pseudoaddiction” is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids:

- | | |
|-----------------|--|
| Actavis | a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted “pseudoaddiction.” |
| Cephalon | b. Cephalon sponsored FSMB’s Responsible Opioid Prescribing (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding are all signs of “pseudoaddiction.” Cephalon also spent \$150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. |
| Endo | <p>c. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled <i>Avoiding Opioid Abuse While Managing Pain</i> (2007). Endo’s internal planning documents describe the purpose of distributing this book as to “[i]ncrease the breadth and depth of the Opana ER prescriber base.” The book claims that when faced with signs of aberrant behavior, the doctor should regard it as “pseudoaddiction” and thus, increasing the dose in most cases . . . should be the clinician’s first response.” (emphasis added).</p> <p>d. Endo spent \$246,620 to buy copies of FSMB’s Responsible Opioid Prescribing (2007), which was distributed by Endo’s sales force. This book asserted that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than</p> |

⁸² John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb.19, 2012).

one doctor to obtain opioids, and hoarding, are all signs of “pseudoaddiction.”

Janssen

- e. From 2009 to 2011 Janssen’s website, Let’s Talk Pain, stated that “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated” and that “[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” (emphasis added).

Purdue

- f. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described “pseudoaddiction” as a concept that “emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”
- g. Purdue distributed to physicians, at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct, including “illicit drug use and deception” it defined as indicative of “pseudoaddiction” or untreated pain. It also states: “Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when *pain is undertreated*. . . . Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be *distinguished from true addiction* in that the behaviors resolve when the pain is effectively treated.” (Emphasis added.)
- h. Purdue sponsored FSMB’s *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name, “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of “pseudoaddiction.” Purdue also spent over \$ 100,000 to support distribution of the book.
- i. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which states: “Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated*. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.” (Emphasis added.)

E. Defendants and their third-party allies claimed withdrawal could be simply managed.

342. Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

343. In an effort to underplay the risk and impact of addiction, Defendants and their third-party allies frequently claim that, while patients become “physically” dependent on opioids, physical dependence can be addressed by gradually tapering patients’ doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

344. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

345. Each of the publications and statements below falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

- | | |
|----------------|---|
| Actavis | a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled “simply” and that it can be done at home. Actavis’s sales representative training claimed opioid withdrawal would take only a week, even in addicted patients. |
| Endo | b. A CME sponsored by Endo, titled <i>Persistent Pain in the Older Adult</i> , taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days. |
| Janssen | <p>c. A Janssen PowerPoint presentation used for training its sales representatives titled “Selling Nucynta ER” indicates that the “low incidence of withdrawal symptoms” is a “core message” for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use; Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER.</p> <p>d. Janssen sales representatives told Plaintiff’s prescribers that patients on Janssen’s drugs were less susceptible to withdrawal than those on other opioids.</p> |

- Purdue**
- e. Purdue sponsored *APF's A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.
 - f. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that the effects of withdrawal from opioid use can be successfully managed.
 - g. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism.

F. Defendants and their third-party allies misrepresented that increased dosage poses no significant additional risks.

346. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

347. Defendants and their third-party allies claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

348. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

349. Each of the following claims suggests that high-dose opioid therapy is safe:

- | | |
|-----------------|--|
| Actavis | a. Documents from a 2010 sales training indicate that Actavis trained its sales force that “individualization” of opioid therapy depended on increasing doses “until patient reports adequate analgesia” and to “set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose.” Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician “comfort level,” which could be overcome or used as a tool to induce them to switch to Actavis’s opioid, Kadian. |
| Cephalon | <p>b. Cephalon sponsored APF’s <i>Treatment Options: A Guide for People Living with Pain</i> (2007), which claimed that some patients “need” a larger dose of their opioid, regardless of the dose currently prescribed.</p> <p>c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, <i>Optimizing Opioid Treatment for Breakthrough Pain</i>, which was offered online by Medscape, LLC from September 28, 2007 through</p> |

December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.

- d. Cephalon sales representatives assured prescribers that wrote opioid prescriptions paid for by the Workers' Compensation Payors that opioids were safe, even at high doses.
- Endo**
 - e. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurred, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.
 - f. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased You won't 'run out' of pain relief."
- Janssen**
 - g. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."
- Purdue**
 - h. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.
 - i. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dose escalations are "sometimes necessary," even indefinitely high ones. This suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online.
 - j. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a

larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses.

- k. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses.
- l. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

G. Defendants and their third-party allies deceptively omitted or minimized adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

350. Each of the Defendants' misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"⁸³ hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids

⁸³ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).⁸⁴

351. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over the counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

⁸⁴ Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction ... death, ... hyperalgesia, hypogonadism . . . mood altered . . . overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

352. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

353. Each of the following reflects Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

- | | |
|-----------------|---|
| Actavis | <ul style="list-style-type: none"> a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs. b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons. c. Kadian sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors were more toxic than opioids. |
| Cephalon | <ul style="list-style-type: none"> d. Cephalon sponsored APF's <i>Treatment Options: A Guide for People Living with Pain</i> (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. <i>Treatment Options</i> also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. e. Cephalon sales representatives told prescribers that wrote opioid prescriptions paid for by the Workers' Compensation Payors that NSAIDs were more toxic than Cephalon's opioids. |
| Endo | <ul style="list-style-type: none"> f. Endo distributed a "case study" to prescribers titled <i>Case Challenges in Pain Management: Opioid Therapy for Chronic Pain</i>. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead. |

- g. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called "*Pain: Opioid Therapy*." This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.
- h. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.
- i. Endo sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that NSAIDs were more toxic than opioids.
- j. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.
- k. Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.
- l. Janssen sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors that Nucynta was not an opioid, making

Janssen

it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.

Purdue

- m. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.
- n. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.
- o. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013; The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.
- p. Purdue sales representatives told prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors NSAIDs were more toxic than opioids.

H. Purdue misleadingly promoted Oxycontin as providing 12 hours of relief.

354. In addition to making the deceptive statements above, Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action.

355. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release

gradually tapers, as illustrated in the following chart, which was, upon information and belief, adapted from Purdue's own sales materials:⁸⁵

OxyContin PI Figure, Linear y-axis

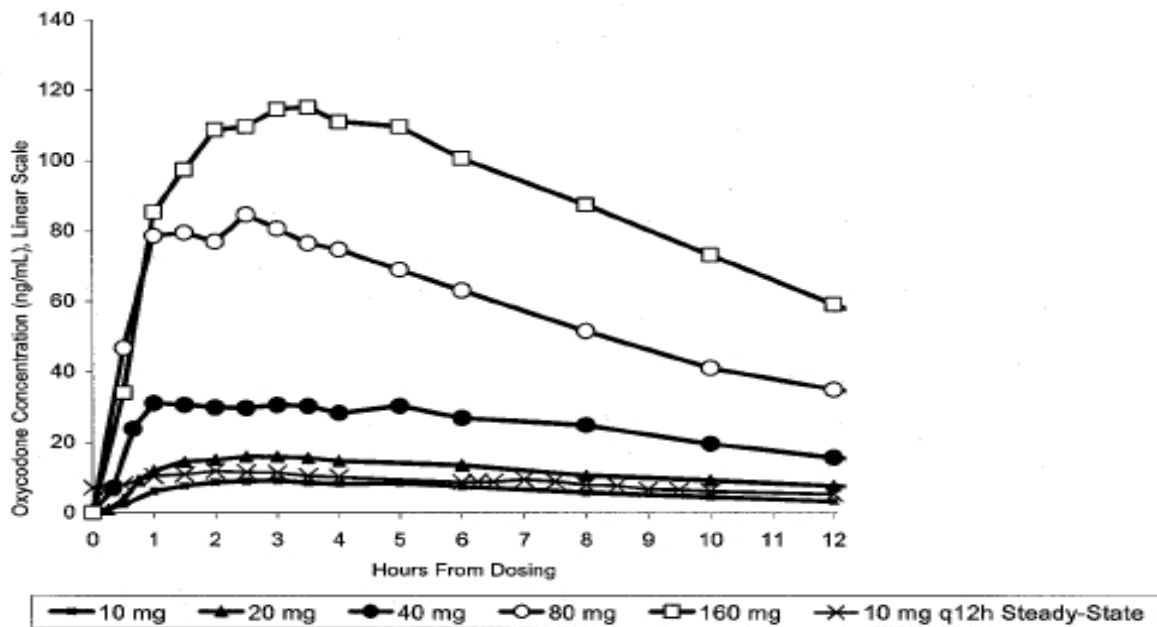


Figure 1

The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the 12 hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

356. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly

⁸⁵ Jim Edwards, "How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power," CBSNews.com, Sept. 28, 2011. The 160 mg dose is no longer marketed. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

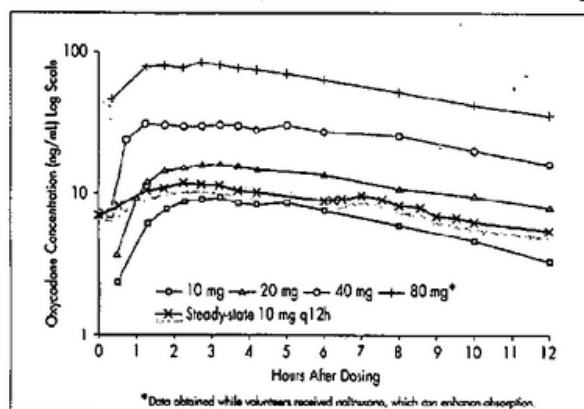
half of the powerful opioid—OxyContin is roughly twice as powerful as morphine—triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full 12 hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. (The FDA found in 2008 that a “substantial number” of chronic pain patients will experience “end-of-dose failure” with OxyContin.) The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

357. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full 12 hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart depicting plasma levels on a logarithmic scale. The chart minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time

Consistent Plasma Levels Over 12 Hours

Plasma concentrations (ng/mL) over time of various dosage strengths



Steady state achieved within 24 to 36 hours

• OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids

358. Subsequently other Purdue advertisements also emphasized “Q12h” (meaning twice-daily) dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. Other advertisements that ran in the 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin, with “Q12h” handwritten for emphasis.

359. The fact that OxyContin did not provide pain relief for a full 12 hours was known to Purdue, and Purdue’s competitors, but was not disclosed to general practitioners. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two (which would have compensated for end-of-dose failure) was set out in Purdue’s internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.⁸⁶ Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position

⁸⁶ MEDWATCH refers to the FDA’s voluntary adverse event reporting system.

its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

360. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers who wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors were not informed of risks relating to addiction, and that they received the misleading message that OxyContin would be effective for treating chronic pain for the advertised duration. Furthermore, doctors would compensate by increasing the dose or prescribing “rescue” opioids, which had the same effect as increasing the amounts of opioids prescribed to a patient.^{87, 88}

⁸⁷ Purdue’s *Clinical Issues in Opioid Prescribing*, put out in 2005 under Purdue’s unbranded *Partners Against Pain* banner, states that “it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing.” References to “rescue” medication appear in publications Purdue sponsored such as APF’s *A Policymaker’s Guide* (2011) and the 2013 CME *Overview of Pain Management Options*.

⁸⁸ The Connecticut Attorney General’s office filed a citizens’ petition with the FDA on January 27, 2004, requesting that the OxyContin label be amended with a warning not to prescribe the drug more than twice daily as a means of compensating for end-of-dose failure. The FDA denied this request on September 11, 2008. The FDA found that the state had failed to present sufficient evidence that more frequent dosing caused adverse outcomes, but the FDA did not challenge the Connecticut finding that end-of-dose failure of OxyContin was prevalent. Indeed, the FDA found that end-of-dose failure affected a “substantial” number of chronic pain patients prescribed OxyContin.

VI. Each Manufacturing Defendant engaged in deceptive marketing, both branded and unbranded, that targeted and reached prescribers, including prescribers of patients receiving workers' compensation benefits.

361. The Manufacturing Defendants—with the aid the Front Groups and KOLs—were able to affect a sea change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain. As set forth below, each Defendant contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which that Defendant exercised editorial control. These deceptive and misleading statements were directed to, and reached, prescribers with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

362. The Manufacturing Defendants engaged in their deceptive marketing campaign, both nationwide and specifically to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors, using a number of strategies. The Manufacturing Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. The Manufacturing Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they are disseminated by the Manufacturing Defendants and relate to their drugs, these materials are considered “labeling” within the meaning of 21 C.F.R. § 1.3(a), which means Defendants are liable for their content.

363. The misrepresentations received by doctors constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. Defendants were aware of each of these misrepresentations, and Defendants approved of them and oversaw their dissemination at the national, corporate level.

A. Actavis

364. As described below, Actavis promoted its branded opioid, Kadian, through a highly deceptive marketing campaign, carried out principally through its sales force and recruited physician speakers. As internal documents indicate, this campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and indeed incorporated each of the types of deceptive messages. Based on the highly coordinated and uniform nature of Actavis's marketing, Actavis conveyed these deceptive messages to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. Actavis did so with the intent that prescribers and/or consumers would rely on the messages in choosing to use opioids to treat chronic pain.⁸⁹

(a) Actavis' deceptive direct marketing.

365. To help devise its marketing strategy for Kadian, Actavis commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005

⁸⁹ Actavis also sold various generic opioids, including Norco, which were widely prescribed, and benefited from Actavis's overall promotion of opioids, but were not directly marketed by sales representatives.

were (i) overcoming “concerns regarding the safety and tolerability” of opioids, and (ii) the fact that “physicians have been trained to evaluate the supporting data before changing their respective practice behavior.” To address these challenges, the report advocated a “[p]ublication strategy based on placing in the literature key data that influence members of the target audience” with an “emphasis . . . on ensuring that the message is believable and relevant to the needs of the target audience.” This would entail the creation of “effective copy points . . . backed by published references” and “developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile.” According to the report, this would allow physicians to “reach[] a mental agreement” and change their “practice behavior” without having first evaluated supporting data—of which Actavis (and other Defendants) had none.

366. The consulting firm predicted that this manufactured body of literature “w[ould], in turn, provide greater support for the promotional message and add credibility to the brand’s advocates” based on “either *actual* or *perceived* ‘scientific exchange’” in relevant medical literature. (emphasis added). To this end, it planned for three manuscripts to be written during the first quarter of 2005. Of these, “[t]he neuropathic pain manuscript will provide evidence demonstrating KADIAN is as effective in patients with presumptive neuropathic pain as it is in those with other pain types”; “[t]he elderly subanalysis . . . will provide clinicians with evidence that KADIAN is efficacious and well tolerated in appropriately selected elderly patients” and will “be targeted to readers in the geriatrics specialty”; and “[t]he QDF/BID

manuscript will . . . call attention to the fact that KADIAN is the only sustained-release opioid to be labeled for [once or twice daily] use.” In short, Actavis knew exactly what each study would show—and how that study would fit into its marketing plan—before it was published. Articles matching Actavis’s descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society*.

367. To ensure that messages based on this science reached individual physicians, Actavis deployed sales representatives, or detailers, to visit prescribers, including those who would write opioid prescriptions paid for by Plaintiff and other Workers’ Compensation Payors. At the peak of Actavis’s promotional efforts in 2011, the company spent \$6.7 million on detailing.

368. To track its detailers’ progress, Actavis’s sales and marketing department actively monitored the prescribing behavior of physicians. It tracked the Kadian prescribing activity of individual physicians and assessed the success of its marketing efforts by tabulating how many Kadian prescriptions a prescriber wrote after he or she had been detailed. As described below, Kadian monitored numerous physicians that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

369. Actavis also planned to promote Kadian by giving presentations at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice of conferences was also influenced by the host’s past support of opioids. For example, Actavis documents show that Actavis presented

papers concerning Kadian at an annual meeting of AGS because AGS's guidelines "support the use of opioids."

370. Actavis targeted prescribers using both its sales force and recruited physician speakers, as described below.

(b) Actavis' deceptive sales training.

371. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in delivering Actavis's marketing strategies and talking points to individual prescribers.

372. Actavis's strategy and pattern of deceptive marketing is evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally.

373. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in

daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have required them to receive increasing doses: “Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain].” Second, Actavis instructed its sales personnel that opioid “[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose.” Actavis failed to explain to its sales representatives and, through them, to doctors, the greater risks associated with opioids at high doses.

374. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that “NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications” and “can have toxic effects on the kidney.” Accordingly, Actavis coached its sales representatives that “[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy” since “[t]hey should only be taken short term.” By contrast, the corresponding section related to opioids neglects to include a *single* side effect or risk associated with the use of opioids, including from long-term use.

375. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. It represented that “there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction” and, instead, “[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice.” This falsely suggests that few patients would become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors could screen for those patients and safely prescribe to others. To the contrary, opioid addiction affects a significant population of patients; while patients with a history of abuse may be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk.

376. The sales training also noted that there were various “signs associated with substance abuse,” including past history or family history of substance or alcohol abuse, frequent requests to change medication because of side effects or lack of efficacy, and a “social history of dysfunctional or high-risk behaviors including multiple arrests, multiple marriages, abusive relationships, etc.” This is misleading, as noted above, because it implies that only patients with these kinds of behaviors and history become addicted to opioids.

377. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated. Indeed, the AHRQ’s Evidence Report on opioids stated it could identify “[n]o study” that had evaluated the effectiveness of various risk mitigation strategies—including the types of

patient screening implied in Actavis's sales training—on outcomes related to overdose, addiction, abuse or misuse.

378. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of “[p]seudoaddiction,” which were defined as “[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain.” However, the concept of “pseudoaddiction” was unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction.

379. Finally, the 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that “[p]hysical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed.” This, however, overlooks the fact that the side effects associated with opiate withdrawal are severe and a serious concern for *any person* who wishes to discontinue long-term opioid therapy.

380. The Kadian Learning System module dates as of July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers even before then. A July 2010 “Dear Doctor” letter issued by the FDA indicated that “[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian].” Certain risks that were misrepresented included the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids” and, specifically, the risk that “[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with

addiction disorders and are subject to criminal diversion.” The FDA also took issue with an advertisement for its misrepresenting Kadian’s ability to help patients “live with less pain and get adequate rest with less medication,” when the supporting study did not represent “substantial evidence or substantial clinical experience.”

381. Actavis’s documents also indicate that the company continued to deceptively market its drugs after 2010. Specifically, a September 2012 Kadian Marketing Update, and the “HCP Detail” aid contained therein, noted that Kadian’s “steady state plasma levels” ensured that Kadian “produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations” than other opioids.

382. Actavis also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the “steady-state” message. That same survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by Actavis’s messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was “without the addictive potential” and wouldn’t “be posing high risk for addiction.” As a result, Actavis’s marketing documents celebrated a “perception” among doctors that Kadian had “low abuse potential”.

383. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits. These

guidelines deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

(c) Actavis' deceptive speaker training.

384. Actavis also relied on speakers—physicians whom Actavis recruited to market opioids to their peers—to convey similar marketing messages. Actavis set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up “power lunch teleconferences” connecting speakers to up to 500 participating sites nationwide. Actavis sales representatives, who were required to make a certain number of sales visits each day and week, saw the definition of sales call expanded to accommodate these changes; such calls now included physicians’ “breakfast & lunch meetings with Kadian advocate/speaker.”

385. A training program for Actavis speakers included training on many of the same messages found in the Kadian Learning System, as described below. The deceptive messages in Actavis’s speakers’ training are concerning for two reasons: (a) the doctors who participated in the training were, themselves, prescribing doctors, and the training was meant to increase their prescriptions of Kadian; and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

386. Consistent with the training for sales representatives, Actavis’s speakers’ training falsely minimized the risk of addiction posed by long-term opioid use. Actavis claimed, without scientific foundation, that “[o]pioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction.” The

training also deceptively touted the effectiveness of “Risk Tools,” such as the Opioid Risk Tool, in determining the “risk for developing aberrant behaviors” in patients being considered for chronic opioid therapy. In recommending the use of these screening tools, the speakers’ training neglected to disclose that none of them had been scientifically validated.

387. The speakers’ training also made reference to “pseudoaddiction” as a “[c]ondition characterized by behaviors, such as drug hoarding, that outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain.” It then purported to assist doctors in identifying those behaviors that *actually* indicated a risk of addiction from those that did not. Behaviors it identified as “[m]ore suggestive of addiction” included “[p]rescription forgery,” “[i]njecting oral formulations,” and “[m]ultiple dose escalations or other nonadherence with therapy despite warnings.” Identified as “[l]ess suggestive of addiction” were “[a]ggressive complaining about the need for more drugs,” “[r]equesting specific drugs,” “[d]rug hoarding during periods of reduced symptoms,” and “[u]napproved use of the drug to treat another symptom.” By portraying the risks in this manner, the speakers’ training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

388. The speakers’ training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs. For example, it asserted that “Acetaminophen toxicity is a major health concern.” The slide further warned that

“Acetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 U.S. Subjects with acute liver failure between 1998-2003,” and was titled “Opioids can be a safer option than other analgesics.” However, in presenting the risks associated with opioids, the speakers’ training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines. As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

389. The speakers’ training also misrepresented the risks associated with increased doses of opioids. For example, speakers were instructed to “[s]tart low and titrate until patient reports adequate analgesia” and to “[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose.” However, the speakers’ training neglected to warn speakers (and speakers bureau attendees) that patients on high doses of opioids are more likely to suffer adverse events.

iv. Actavis’ deceptive statements to prescribers and patients.

390. The misleading messages and training materials Actavis provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and

included prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. Actavis's nationwide messages reached these prescribers in a number of ways. For example, they were carried to these prescribers by Actavis's sales representatives during detailing visits as well as made available to patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to prescribers Actavis's paid speakers, who were required by Actavis policy and by FDA regulations to stay true to Actavis's nationwide messaging.

391. Once trained, Actavis's sales representatives and speakers were directed to, and did, visit these potential prescribers to deliver their deceptive messages. These contacts are demonstrated by Actavis's substantial effort in tracking the habits of individual physicians that wrote prescriptions paid for Plaintiff and the Workers' Compensation Payors prescribing Kadian, and by the direct evidence of Actavis detailing these prescribers.

392. Actavis tracked, in substantial detail, the prescribing behavior of physicians prescribing opioid prescriptions to claimants.

B. Cephalon

393. At the heart of Cephalon's deceptive promotional efforts was a concerted and sustained effort to expand the market for its branded opioids, Actiq and Fentora, far beyond their FDA-approved use in opioid-tolerant cancer patients. Trading on their rapid-onset formulation, Cephalon touted its opioids as the answer to "breakthrough pain"—a term its own KOL allies planted in the medical

literature—whether cancer pain or not. Cephalon promoted this message through its sales force, paid physician speakers, advertisements, and CMEs, even after the FDA issued the company warnings and rejected an expanded drug indication.

394. Even as it promoted Actiq and Fentora off-label, Cephalon also purveyed many of the deceptive messages described above. It did so both directly—through detailing visits and speaker programs—and through the publications and CMEs of its third-party partners. These messages included misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids.

395. Based on the highly coordinated and uniform nature of Cephalon's marketing, Cephalon conveyed these deceptive messages to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. The materials that Cephalon generated in collaboration with third-parties were also distributed or made available nationally and specifically to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. Cephalon distributed these messages and/or facilitated their distribution with the intent that prescribers would rely on them in choosing to use opioids to treat chronic pain.

(a) Cephalon's deceptive direct marketing.

396. Like the other Defendants, Cephalon directly engaged in misleading and deceptive marketing of its opioids through its sales force and branded advertisements. These messages were centrally formulated and intended to reach

prescribers nationwide, including those that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. Cephalon also spent the money necessary to aggressively promote its opioid drugs, setting aside \$20 million to market Fentora in 2009 alone.

ii. Cephalon's fraudulent off-label marketing of Actiq and Fentora.

397. Chief among Cephalon's direct marketing efforts was its campaign to deceptively promote its opioids for off-label uses. Cephalon reaped significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs— Actiq or Fentora—is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction, and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed. This resulted in prescriptions written and paid and, grievously, caused patients to be injured and die. Cephalon's efforts to expand the market for its drugs beyond cancer pain extended to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

398. Cephalon’s Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq “tastes like the most delicious candy you ever ate.”⁹⁰

399. Actiq is appropriately used only to treat “breakthrough” cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Actiq is a rapid-onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid tolerant, meaning patients who have taken specific doses of opioids for a week or longer and whose systems have acclimated to the drugs.

400. In 1998, the FDA approved Actiq “**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”⁹¹ (emphasis in FDA document). Because of Actiq’s dangers, wider, off-label uses—as the FDA label makes clear—are not permitted:

This product ***must not*** be used in opioid non-tolerant patients because life-threatening respiratory depression and death could

⁹⁰ See John Carreyrou, *Narcotic ‘Lollipop’ Becomes Big Seller Despite FDA Curbs*, Wall St. J., Nov. 3, 2006.

⁹¹ FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf (accessed November 18, 2019).

occur at any dose in patients not on a chronic regimen of opioids. For this reason, ACTIQ is contraindicated in the management of acute or postoperative pain.⁹²

401. Actiq and Fentora are thus intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain. Unlike other drugs, of which off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off-label use for opioid naïve patients is barred by the FDA, as their labels make clear.

402. Notwithstanding the drug's extreme potency and related dangers, and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain—an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer and for which it was not approved, appropriate, or safe.

403. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached \$412 million, making it Cephalon's second-highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded \$500 million by 2006.

⁹² Actiq Drug Label, July 2011. The 1998 version does not substantively differ: "Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contra- indicated in the management of acute or postoperative pain. This product ***must not*** be used in opioid non-tolerant patients." (emphasis in original).

404. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application (“NDA”) to the FDA for approval. Like Actiq, Fentora is an extremely powerful and rapid-onset opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth.

405. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Fentora’s unusually strong and detailed black box warning label—the most serious medication warning required by the FDA—makes clear that, among other things:

Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose.

Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.⁹³

406. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it had developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to

⁹³ Fentora Drug Label, February 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021947s008lbl.pdf (accessed November 18, 2019).

selling Fentora to the very same physicians for uses that would necessarily and predictably be off label. Cephalon's marketing of Actiq therefore "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally—not breakthrough cancer pain in particular—from Actiq. Cephalon also developed a plan in 2007 to target elderly chronic pain patients via a multi-city tour with stops at AARP events, YMCAs, and senior living facilities.

407. On February 12, 2007, only four months after the launch, Cephalon CEO Frank Baldino told investors:

[W]e've been extremely pleased to retain a substantial portion, roughly 75% of the `rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.⁹⁴

408. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities"—treating breakthrough cancer pain and:

The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower

⁹⁴ See *Cephalon Q4 2006 Earnings Call Transcript*, Seeking Alpha (February 12, 2007, 8:48 PM EST) at 5.

back pain and breakthrough neuropathic pain. . . .

. . . .

We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . [opioids are] widely used in the treatment of. . . non-cancer patients

. . . .

Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.

We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.

In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.⁹⁵

409. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other “serious adverse events” connected with the use of Fentora, indicating that “[t]hese deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product

⁹⁵ See *Cephalon Q1 2007 Earnings Call Transcript*, Seeking Alpha (May 1, 2007, 8:48 PM EST) at 23, <http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?page=1> (accessed November 18, 2019).

substitution.”⁹⁶ The warning did not mention Cephalon’s deliberate role in the “improper patient selection.”

410. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora should be prescribed only for approved conditions and that dose guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label uses. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that, because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.⁹⁷

411. Notwithstanding the regulatory scrutiny, Cephalon’s off-label marketing continued. Cephalon’s 2008 internal audit of its Sales & Marketing Compliance Programs concluded that marketing and tactical documents, as written, may be construed to promote off-label uses. The same report acknowledged that Cephalon lacked a process to confirm that speakers’ program participants were following Cephalon’s written, formal policies prohibiting off-label promotion, and that “non-compliant [Cephalon Speaker Programs] may be taking place.” Moreover,

⁹⁶ Letter from Jeffrey M. Dayno, M.D., Vice President, Medical Services, Cephalon, Inc. to Healthcare Providers (Sept. 10, 2007).

⁹⁷ FDA Public Health Advisory, *Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007).

the report acknowledged that Cephalon’s “call universe” may include “inappropriate prescribers”—prescribers who had nothing to do with cancer pain.

412. Cephalon filed a supplemental new drug application, (“sNDA”), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.⁹⁸ Cephalon’s application also conceded that “[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain.” *Id.*

413. In response to Cephalon’s application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.⁹⁹ By a vote of 17-3, the relevant Advisory Committee—a panel of outside experts—voted against recommending approval of Cephalon’s sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon’s application and requested, in light of Fentora’s already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora’s Risk Management Program. In December 2008, the FDA followed that request with a

⁹⁸ See *Fentora CII: Advisory Committee Briefing Document*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008).

⁹⁹ See Yoo Jung Chang & Lauren Lee, *Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System (“AERS”) Database*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008).

formal request directing Cephalon to submit a Risk Evaluation and Mitigation Strategy for Fentora.

414. Undeterred by the rejection of its NDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade of Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not only those who were opioid tolerant.

415. On March 26, 2009, the Drug Marketing, Advertising, and Communications Division of the FDA (“DDMAC”) issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug.¹⁰⁰ Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said “[l]earn about treating breakthrough pain in patients with cancer,” was improper because it “misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy . . . when this is not the case.”

416. DDMAC emphasized that Fentora’s label was limited to cancer patients with breakthrough pain “*who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.*” (emphasis in

¹⁰⁰ Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009).

original). DDMAC explained that the advertisement was “especially concerning given that Fentora must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids.” (Emphasis in original). DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company’s advertisements were “misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate any risk information associated with the use” of the drug. (emphasis in original).

417. Cephalon’s own market research studies confirm that its Fentora promotions were not focused on physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an “adequate” market potential for Fentora. These studies’ central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be

an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

418. Cephalon was well aware that physicians were prescribing Fentora for off-label uses.

419. Cephalon was also aware that its detailing had an impact on prescription rates.

420. In 2011, Cephalon wrote and copyrighted an article titled "2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)" that was published in *Pain Medicine News*.¹⁰¹ The article promoted Cephalon's drugs for off-label uses by stating that the "judicious use of opioids can facilitate effective and safe management of chronic pain" and noted that Fentora "has been shown to be effective in treatment of [break through pain] associated with multiple causes of pain," not just cancer.¹⁰²

iii. Cephalon's misrepresentation of the risks associated with the use of opioids for the long-term treatment of chronic pain.

421. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension, and reaped the benefits, of Cephalon's generally deceptive promotion of opioids for chronic pain.

¹⁰¹ <http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rem>s (accessed November 18, 2019).

¹⁰² *Id.*

422. There is insufficient scientific evidence to corroborate a link between chronic opioid therapy and increased functionality. There is however, sufficient evidence to show increased risks of overdose and addiction.¹⁰³

423. Along with deploying its sales representatives, Cephalon used speakers' bureaus to help reach prescribers. The company viewed each treating physician as a vehicle to generate prescriptions—whether written by that physician directly or caused indirectly by his or her influence over other physicians.

424. Having determined that speakers were an effective way to reach prescribers, Cephalon set to work ensuring that its speakers would disseminate its misleading messages. Cephalon did not disclose to speakers that, even when these tools are applied, they are unable to control for the risk of addiction.

425. As with the other Defendants, Cephalon deployed the made-up concept of “pseudoaddiction” to encourage prescribers to address addictive behavior in the worst way possible—with more opioids.

426. Working with FSMB, Cephalon also trained its speakers to turn doctors' fear of discipline on its head—doctors, who believed that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with pain. Through this messaging, Cephalon aimed to normalize the prescribing of

¹⁰³ Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 347 New Eng. J. Med. 1501-04 (2016).

opioids for chronic pain and failed to acknowledge the serious risks of long-term opioid use and its inappropriateness as a front-line treatment for pain.

427. Finally, Cephalon also developed a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which deceptively minimized the risks of addiction from the long-term use of opioids. Specifically, the guidebook claimed that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids,” which is dangerously false. Cephalon distributed the guidebook broadly, and it was available to, and intended to reach, prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

428. The misleading messages and materials Cephalon provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors. Cephalon’s nationwide messages have reached these prescribers in a number of ways. For example, they were delivered by Cephalon’s sales representatives in detailing visits and made available to patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to prescribers by Cephalon’s paid speakers, who were required by Cephalon policy to stay true to the company’s nationwide messaging.

iv. Cephalon’s deceptive third-party statements.

429. Like the other Defendants, Cephalon also relied on third parties to disseminate its messages through deceptive publications and presentations. By funding, developing and reviewing the content, and distributing and facilitating the distribution of these messages, Cephalon exercised editorial control over them. Cephalon, in some instances, used its sales force to directly distribute certain publications by these Front Groups and KOLs, rendering those publications “labeling” within the meaning of § 21 C.F.R. § 1.3(a) and making Cephalon responsible for their contents. Cephalon also deployed its KOLs as speakers for talks and CMEs to selected groups of prescribers.

430. Cephalon’s relationships with several such Front Groups and KOLs—and the misleading and deceptive publications and presentations those relationships generated—are described below.

431. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB’s *Responsible Opioid Prescribing*, which was drafted by Dr. Fishman. Dr. Fishman was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman’s work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

432. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman’s work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact on a patient’s ability to function, relieving

pain—alone—would “reverse that effect and improve function.” However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

433. *Responsible Opioid Prescribing* also misrepresented the likelihood of addiction by mischaracterizing drug-seeking behavior as “pseudoaddiction.” It explained that “requesting drugs by name,” engaging in “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding were all signs of “pseudoaddiction” and are likely the effects of undertreated pain, rather than true addiction. There is no scientific evidence to support the concept of “pseudoaddiction,” and any suggestion that addictive behavior masquerades as “pseudoaddiction” is false.

434. Cephalon spent \$150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide. These were available to, and intended to, reach prescribers and pharmacists that wrote prescriptions for and dispensed prescriptions to, respectively, the claimants of Plaintiff and the Workers’ Compensation Payors.

435. Cephalon also exercised considerable control over the Front Group APF, which published and disseminated many of the most egregious falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, are described in detail below.

436. Documents indicate that Cephalon provided APF with substantial assistance in publishing deceptive information regarding the risks associated with the use of opioids for chronic pain. An April 3, 2008 Fentora Assessment Strategy Tactics Team Meeting presentation outlines Cephalon's strategy to prepare for a meeting at which the FDA Advisory Committee would consider expanding the indication of Fentora to include chronic non-cancer pain. Cephalon prepared by "reaching out to third-party organizations, KOLs, and patients to provide context and, where appropriate, encourage related activity." First among the Front Groups listed was APF.

437. Cephalon was among the drug companies that worked with APF to "educate" the Institute of Medicine of the National Academies (IOM) on issues related to chronic opioid therapy. APF President Will Rowe circulated a document to Cephalon and other drug company personnel that contained key message points and suggested that they "[c]onsider using this document in your communications with the members of the IOM Committee." According to Rowe, recipients should "consider this a working document which you can add to or subtract from." Rowe also advised that, if recipients "have an ally on that Committee," they should "consider sharing this document with that person."

438. Cephalon personnel responded enthusiastically, with Cephalon's Associate Director for Alliance Development stating her belief that "the document does a good job of bringing together many important ideas." Cephalon reviewed and directed changes to this document, with the Cephalon Associate Director thanking

Rowe “for incorporating the points we had raised.” The close collaboration between Cephalon and APF on this project demonstrates their agreement to work collaboratively to promote the use of opioids as an appropriate treatment for chronic pain.

439. Cephalon’s influence over APF’s activities was so pervasive that APF’s President, Will Rowe, even reached out to Defendants—including Cephalon—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine.

440. Starting in 2007, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain*.¹⁰⁴ It is rife with misrepresentations regarding the risks, benefits, and superiority of opioids.

441. For example, *Treatment Options* deceptively asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids “give [pain patients] a quality of life [they] deserve.” There is no scientific evidence corroborating that statement, and such statements are, in fact, false. Available data demonstrate that patients on chronic opioid therapy are actually *less likely* to participate in life activities like work.

442. *Treatment Options* also claims that addiction is rare and is evident from patients’ conduct in self-escalating their doses, seeking opioids from multiple

¹⁰⁴ <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (accessed November 18, 2019)

doctors, or stealing the drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be avoided through the use of screening tools, like “opioid agreements,” which can “ensure [that patients] take the opioid as prescribed.” Nowhere does *Treatment Options* explain to patients and prescribers that neither “opioid agreements” nor any other screening tools have been scientifically validated to decrease the risks of addiction, and the publication’s assurances to the contrary are false and deceptive.

443. *Treatment Options* also promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAID overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have “no ceiling dose,” which is beneficial since some patients “need” larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids.

444. Additionally, *Treatment Options* warns that the risks associated with NSAID use increase if NSAIDs are “taken for more than a period of months,” but deceptively omits any similar warning about the risks associated with the long-term use of opioids. This presentation paints a misleading picture of the risks and benefits of opioid compared with alternate treatments.

445. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. It was intended to reach prescribers and pharmacists that wrote prescriptions for and dispensed opioids, respectively, to the claimants of Plaintiff and the Workers' Compensation Payors.

446. Cephalon also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated by seemingly neutral scientific support.

447. Employing these tactics, Cephalon caused the term “breakthrough pain”—a term it seeded in the medical literature—to be used in articles published by practitioners and clinicians it supported. With funding from Cephalon, for example, Dr. Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of Cephalon's Fentora. The article was published in the nationally circulated *Journal of Pain* in 2006 and helped drive a surge in Fentora prescriptions.

448. The concept of “breakthrough pain” ultimately formed the sole basis for the central theme of promotional messages Cephalon cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which begin to work very quickly but last only briefly. Neither of these drugs had a natural place in the treatment of chronic pain before Cephalon's marketing campaign changed medical practice. A recent literature survey of articles describing non-cancer breakthrough pain calls into question the validity of the concept, suggesting it is not a distinct

pain condition but a hypothesis to justify greater dosing of opioids. In other words, Cephalon conjured the science of breakthrough pain in order to sell its drugs.

449. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006.¹⁰⁵ These spikes coincide with FDA's approval of Actiq and Fentora.

450. Cephalon developed sophisticated plans for the deployment of its KOLs, broken down by sub-type and specialty, to reach targeted groups of prescribers through CMEs. Cephalon used the CME programs it sponsored to deceptively portray the risks related to the use of opioids to treat chronic non-cancer pain and promote the off-label use of Actiq and Fentora.

451. In 2007 and 2008, Cephalon sponsored three CMEs that each positioned Actiq and Fentora as the only "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs used only the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME knew it referred only to Actiq or Fentora.

452. The CMEs taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. Optimizing Opioid Treatment for Breakthrough Pain,

¹⁰⁵ Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut, Georgetown U. Med. Ctr. (June 25, 2010).

offered online by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Webster and M. Beth Dove. It recommends prescribing a “short-acting opioid” (e.g., morphine, hydromorphone, oxycodone) “when pain can be anticipated,” or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (i.e., Actiq) or fentanyl effervescent buccal tablet (i.e., Fentora): “Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well.”

453. Optimizing Opioid Treatment for Breakthrough Pain not only deceptively promoted Cephalon’s drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME misrepresented that Actiq and Fentora would help patients regain functionality by advising that they improve patients’ quality of life and allow for more activities when taken in conjunction with long-acting opioids. The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids.

454. Around the same time, Dr. Webster was receiving nearly \$2 million in funding from Cephalon.

455. Optimizing Opioid Treatment for Breakthrough Pain was available online and was intended to reach prescribers that wrote opioid prescriptions for the claimants of Plaintiff and the Workers' Compensation Payors.

456. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online between March 31, 2008, and March 31, 2009, by Medscape, LLC. The direct result of Cephalon's funding was a purportedly educational document that echoed Cephalon's marketing messages. The CME deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid Treatment* CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

457. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.¹⁰⁶ It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommended dispensing "rapid onset

¹⁰⁶ <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain> (accessed November 18, 2019).

opioids” for “episodes that occur spontaneously” or unpredictably, including “oral transmucosal fentanyl,” *i.e.*, Actiq, and “fentanyl buccal tablet,” *i.e.*, Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon’s speakers bureau.¹⁰⁷ Dr. Fine also received funding from Cephalon for consulting services.

458. *Opioid-Based Management of Persistent and Breakthrough Pain* was available to and was intended to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

459. Cephalon’s control over the content of these CMEs is apparent based on its advance knowledge of their content. A December 2005 Cephalon launch plan set forth key “supporting messages” to position Fentora for its product launch. Among them was the proposition that “15-minute onset of action addresses the unpredictable urgency of [breakthrough pain].” Years later, the same marketing messages reappeared in the Cephalon-sponsored CMEs described above. Echoing the Cephalon launch plan, *Optimizing Opioid Treatment for Breakthrough Pain* stated that “[t]he unpredictability of [breakthrough pain] will strongly influence the choice of treatment” and that Fentora “delivers an onset of analgesia that is similar to [Actiq] at ≤ 15 minutes.” Similarly, *Opioid-Based Management of Persistent and*

¹⁰⁷14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

Breakthrough Pain defined “breakthrough pain” as “unpredictable,” over a table describing both cancer and non-cancer “breakthrough pain.”

460. Cephalon tracked the effectiveness of its deceptive marketing through third parties, demonstrating that Cephalon not only planned for, but depended upon, their activities as a key element of its marketing strategy. These programs were available to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors, and, based on the uniform and nationwide character of Cephalon’s marketing, featured the same deceptive messages described above.

v. Cephalon’s deceptive third-party statements to prescribers and patients.

461. Cephalon used various measures to disseminate its deceptive statements regarding the risks of off-label use of Actiq and Fentora and the risks, benefits, and superiority of opioids to patients and prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

462. Cephalon’s speakers regularly held talks for prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors. These talks followed the same deceptive talking points covered in Cephalon’s speakers’ training.

463. Cephalon also targeted prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors through the use of its sales force.

464. Given that Cephalon's own studies demonstrated that the overwhelming majority of oncologists diagnose and treat breakthrough cancer pain themselves, Cephalon knew the only purpose of representatives meeting with these prescribers was to promote off-label use. Based on the uniform and nationwide character of Cephalon's marketing, Cephalon's deceptive messages would have been disseminated to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors by Cephalon's sales representatives during these events.

465. Sales representatives, and the misrepresentations on which they were trained, drove significant Fentora sales.

C. Endo

466. Endo promoted its opioids through the full array of marketing channels. The company deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. Misleading claims about the purportedly lower abuse potential of Opana ER was featured prominently in this campaign. Endo also made many other deceptive statements and omissions. These included deceptive messages about functional improvement, addiction risk, "pseudoaddiction," addiction screening tools, and the safety of alternatives to opioids.

467. At the same time, Endo also relied on third-party partners to promote the safety, efficacy, and superiority of opioids generally, through a combination of CMEs, websites, patient education pamphlets, and other publications. These

materials echoed the misrepresentations described above, and also made deceptive statements about withdrawal symptoms and the safety of opioids at higher doses.

468. Because of the extensive, highly coordinated and uniform nature of Endo's marketing, it is likely and believed that Endo conveyed these deceptive messages to prescribers that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors. The materials that Endo generated in collaboration with third-parties also were distributed or made available nationwide, and specifically to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. Endo distributed these messages or facilitated their distribution with the intent that prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

(a) Endo's deceptive direct marketing.

469. Like the other Defendants, Endo used deceptive direct marketing to increase the sales of its dangerous opioids. As set forth below, Endo conveyed these deceptive messages in training of its sales force and recruited speakers, who in turn conveyed them to physicians; in a misleading journal supplement; and in unbranded advertising.

470. Endo's promotion of Opana ER relied heavily on in-person marketing, including to prescribers that wrote opioid prescriptions, including those it is believed wrote prescriptions paid for by Plaintiff and other Workers' Compensation Payors. Endo had an aggressive detailing program. In the first quarter of 2010 alone, sales representatives made nearly 72,000 visits to prescribers nationwide to

detail Opana ER. Between 2007 and 2013, Endo spent between \$3 million and \$10 million each quarter to promote opioids through its sales force.

471. Endo's sales representatives, like those of the other Defendants, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

472. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" by more than 45% by the end of that year. Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that Endo's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

473. Endo trained its sales force to make a number of misrepresentations to physicians nationwide, including, it is believed, to physicians that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors. Endo's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that Endo opioids

had a lower potential for abuse because they were “designed to be crush resistant,” despite the fact that “clinical significance of INTAC Technology or its impact on abuse/misuse ha[d] not been established for Opana ER;” and that drug seeking behavior was a sign of undertreated pain rather than addiction.

474. Endo knew that its marketing reached physicians repeatedly because it tracked their exposure. Internal Endo documents dated August 23, 2006 demonstrate that the following percentages of physicians would view an Endo journal insert (or paid supplement) at least 3 times in an 8-month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of OB/GYNs.

475. Endo was not only able to reach physicians through its marketing, but also successfully impart its marketing messages as well. The company found that its promotional materials tripled prescribers’ ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. This was true of marketing that contained deceptions.

476. For example, according to internal Endo documents, up to 10% of physicians it detailed were able to recall, without assistance, the message that Opana ER had “Minimal/less abuse/misuse” potential than other drugs. The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction. Although Opana ER always has been classified under Schedule II as a drug with a “high potential for abuse”, the largest single perceived advantage of Opana ER, according to a survey of 187

physicians who reported familiarity with the drug, was “perceived low abuse potential,” cited by 15% of doctors as an advantage. Low abuse potential was among the deceptive messages that prescribers that wrote opioid prescriptions received, and retained, from Endo sales representatives, including on belief physicians that wrote opioid prescriptions paid for by Plaintiff and other Workers’ Compensation Payors.

477. Endo’s internal documents acknowledged the misleading nature of these statements, conceding that “Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning.” A September 2012 Opana ER Business Plan similarly stated that Endo needed a significant investment in clinical data to support comparative effectiveness, scientific exchange, benefits and unmet need, while citing lack of “head-to-head data” as a barrier to greater share acquisition.

478. Nevertheless, Endo knew that its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescribers of Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for Endo’s marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. Internal Endo documents from May 2008 indicate that Endo expected that each of its sales representatives would generate

19.6 prescriptions per week by the end of 2008. As summarized by a February 2011 report on Opana ER growth trends, Endo's "[a]ggressive detailing [is] having an impact."

479. More broadly, Endo's sales trainings and marketing plans demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of opioids when used to treat chronic pain. Foremost among these messages were misleading claims that the risks of addiction, diversion, and abuse associated with opioids—and Endo's products in particular—were low, and lower than other opioids.

(b) Endo's sale force deceptively minimized the risks of addiction associated with chronic opioid therapy.

480. By way of illustration, Endo's Opana ER INTAC Technology Extended-Release Sell Sheet Implementation Guide, which instructs Endo sales personnel how to effectively "support key messages" related to the marketing of Opana ER, states that it is an "approved message" for sales representatives to stress that Opana ER was "designed to be crush resistant," even though this internal document conceded that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER."

481. Other Endo documents acknowledged the limitations on Opana ER's INTAC technology, conceding that while Opana ER may be resistant to pulverization, it can still be "ground" and "cut into small pieces" by those looking to abuse the drug.

482. Endo's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers that wrote opioid prescriptions for the claimants of Plaintiff and the Workers' Compensation Payors.

483. The only reason to promote the crush resistance of Opana ER was to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. The idea that Opana ER was less addictive than other drugs was the precise message that prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors took from Endo's marketing.

484. On May 10, 2013, the FDA warned Endo that there was no evidence that Opana ER's design "would provide a reduction in oral, intranasal, or intravenous abuse" and that the post-marketing data Endo had submitted to the FDA "are insufficient to support any conclusion about the overall or route-specific rates of abuse." Even though it was rebuked by the FDA, Endo continued to market Opana ER as having been designed to be crush resistant, knowing that this would (falsely) imply that Opana actually was crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused.

485. Endo's sales training and the promotional materials distributed by its sales representatives also minimized the risk of addiction. Endo also circulated education materials that minimized the risk of addiction. For example, Endo

circulated an education pamphlet with the Endo logo titled “Living with Someone with Chronic Pain,” which implied, to persons providing care to chronic pain patients, that addiction was not a substantial concern by stating that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” This pamphlet was downloadable from Endo’s website and accessible to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

486. Endo’s sales training also misrepresented the risks of addiction associated with Endo’s products by implying that Opana’s prolonged absorption would make it less likely to lead to abuse. For example, a presentation titled “Deliver the Difference for the Opana Brand in POA II” sets out that one of the “[k]ey [m]essages” for the Endo sales force was that Opana ER provides “[s]table, steady-state plasma levels for true 12-hour dosing that lasts.” Endo’s sales representatives used this messaging to imply to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors that Opana ER provided “steady state” pain relief, making Opana less likely to incite euphoria in patients and less likely to lead to addiction.

487. Endo further instructed its sales force to promote the misleading concept of “pseudoaddiction,”—*i.e.*, that drug-seeking behavior was not cause for alarm, but merely a manifestation of undertreated pain. In a sales training document titled “Understanding the Primary Care MD and their use of Opioids,” Endo noted that the “biggest concerns” among primary care physicians were

“prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%).” In response to these concerns, Endo instructed its sales representatives to ask whether their customers were “confus[ing] ‘pseudo-addiction’ with ‘drug-seekers’” and how confident they were that their health care providers “know these differences (Tolerance, Dependence, Addiction, Pseudo- Addiction . . .).”

(c) Endo’s sale force deceptively implied that chronic opioid therapy would improve patients’ ability to function.

488. In addition to their deceptive messages regarding addiction, Endo’s promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long- term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to, and does not, improve patients’ function, and, in fact, is often accompanied by serious side effects that degrade function. Endo’s own internal documents acknowledged that claims about improved quality of life were unsubstantiated “off label claims.”

489. Nevertheless, Endo distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front: “Janice is a 46-year-old chef with chronic low back pain. She needs a treatment option with true 12-hour dosing.” The advertisement does not mention the “moderate to severe pain” qualification in Opana ER’s indication, except in the fine print. These advertisements were mailed to prescribers and distributed by

Endo's sales force in detailing visits, which would have included Endo representatives' visits to prescribers.

490. In a 2007 sales tool that was intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named "Bill," a 40-year-old construction worker who was reported to suffer from chronic low back pain. According to the sales tool, Opana ER will make it more likely that Bill can return to work and support his family.

491. Similarly, training materials for sales representatives from March 2009 ask whether it is true or false that "[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself." The materials indicate that this is "[f]alse" because "[t]he overall effect of treatment with opioids is very favorable in most cases."

492. A sales training video dated March 8, 2012 that Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that "chronic pain [. . .] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball game and "[t]here's no substitute for that." This video was shown to Endo's sales force, which adopted its misleading messaging in its nationwide sales approach.

493. Claims of improved functionality were central to Endo's marketing efforts for years. A 2012 Endo Business Plan lists ways to position Opana ER, and among them is the claim that Opana ER will help patients "[m]aintain[] normal

functionality, sleep, [and] work/life/performance productivity” and have a positive “[e]ffect on social relationships.” Indeed, that business plan describes the “Opana ER Vision” as “[t]o make the Opana franchise (Opana ER, Opana, Opana Injection) the choice that maximizes improvement in functionality and freedom from the burden of moderate-to-severe pain.”

iv. Endo’s sale force deceptively presented the risks and benefits of opioids to make them appear safer than other analgesics.

494. Endo further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, Endo distributed a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed “a massive upper gastrointestinal bleed.” The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

495. Endo distributed *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to 116,000 prescribers in 2007, including primary care physicians.

v. Endo’s speakers bureau deceptively minimized the risks of addiction associated with chronic opioid therapy.

496. In addition to its sales representatives’ visits to doctors, Endo also used deceptive science and speaker programs to spread its deceptive messages.

497. Endo leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly \$4 million to promote up to 1,000 speakers programs around the country. Endo contracted with a medical communications firm to operate its speakers bureau program, planning to hold a total of 500 "fee-for-service . . . peer-to-peer promotional programs" for Opana ER in just the second half of 2011, including dinners, lunches and breakfasts. These programs were attended by sales representatives, revealing their true purpose as marketing, rather than educational, events.

498. Endo's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. Endo measured that return on investment in numbers of prescriptions written by physicians who attended the events. One internal Endo document concluded: "[w]e looked at the data for [the] 2011 program and the results were absolutely clear: physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that."

499. These speakers bureau presentations included the very same misrepresentations Endo disseminated through its sales representatives. A 2012 speaker slide deck for Opana ER— on which Endo's recruited speakers were trained and to which they were required to adhere to in their presentations— misrepresented that the drug had low abuse potential, in addition to suggesting that as many as one-quarter of the adult population could be candidates for opioid therapy.

500. In addition, a 2013 training module directed speakers to instruct prescribers that “OPANA ER with INTAC is the only oxymorphone designed to be crush resistant” and advised that “[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe OPANA ER with INTAC.” This was a key point in distinguishing Opana ER from competitor drugs. Although Endo mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that “[t]he generics are not designed to be crush resistant.” This was particularly deceptive given that Opana ER was not actually crush-resistant.

501. In 2009, Endo wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain*. The talk included a slide titled “Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain,” which cited the AAPM/APS Guidelines—and their accompanying misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients’ past abuse histories) while omitting their disclaimer regarding the lack of supporting evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

502. The misleading messages and materials Endo provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and due to the highly coordinated, uniform and extensive nature of Endo’s marketing it is believed

reached and affected prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors in a number of ways. For example, they were carried by Endo's sales representatives during detailing visits as well as made available to patients and prescribers that wrote opioid prescriptions through websites and ads. They also have been delivered to prescribers that wrote opioid prescriptions by Endo's paid speakers, who were required by Endo policy and by FDA regulations to stay true to Endo's nationwide messaging.

vi. Endo's misleading journal supplement.

503. In 2007, Endo commissioned the writing, and paid for the publishing of a supplement available for CME credit in the Journal of Family Practice called Pain Management Dilemmas in Primary Care: Use of Opioids. The supplement deceptively minimized the risk of addiction by emphasizing the effectiveness of screening tools. Specifically, it recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. It also falsely claimed that, through the use of tools like toxicology screens, pill counts, and a "maximally structured approach," even patients at high risk of addiction could safely receive chronic opioid therapy. Endo distributed 96,000 copies of this CME nationwide, and it was available to, and was intended to, reach prescribers, including those, it is believed, that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

vii. Endo's deceptive unbranded advertising.

504. Endo also used unbranded advertisements to advance its goals. By electing to focus on unbranded marketing, Endo was able to make claims about the

benefits of its opioids that the FDA would never allow in its branded materials. The chart below compares an Endo unbranded statement with one of Endo's FDA-regulated, branded statements:

Living with Someone with Chronic Pain (2009) (Unbranded)	Opana ER Advertisement (2011/2012/2013) (Branded)
Patient education material created by Endo	Endo advertisement
<p>"Most health care providers who treat people with pain agree that most people do not develop an addiction problem."</p>	<p>"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit."</p> <p>"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."</p>

viii. Endo's deceptive third-party statements.

505. Endo's efforts were not limited to directly making misrepresentations through its marketing materials, its speakers, and its sales force. Endo believed that support for patient advocacy and professional organizations would reinforce Endo's position as "the pain management company."

506. Prior to, but in contemplation of, the 2006 launch of Opana ER, Endo developed a "Public Stakeholder Strategy." Endo identified "tier one" advocates to

assist in promoting the approval and acceptance of its new extended release opioid. Endo also intended to enlist the support of organizations that would be “favorable” to schedule II opioids from a sales perspective and that engaged in, or had the potential to advocate for, public policy. Endo sought to develop its relationships with these organizations through its funding. In 2008, Endo spent \$1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing (“ASPMN”).

507. APF’s ability to influence professional societies and other third parties is demonstrated by its approach to responding to a citizens’ petition filed with the FDA by the Physicians for Responsible Opioid Prescribing (the “PROP Petition”). The PROP petition, filed by a group of prescribers who had become concerned with the rampant prescribing of opioids to treat chronic pain, asked the FDA to require dose and duration limitations on opioid use and to change the wording of the approved indication of various long-acting opioids to focus on the severity of the pain they are intended to treat.

508. The PROP Petition set off a flurry of activity at Endo. It was understood that Endo would respond to the petition but Endo personnel wondered “[s]hould we . . . consider filing a direct response to this [citizens’ petition] or do you think we are better served by working through our professional society affiliations?” One Endo employee responded: “My sense is the societies are better placed to make a medical case than Endo.” Endo’s Director of Medical Science agreed that “a reply

from an external source would be most impactful.” These communications reflected Endo’s absolute confidence that the professional societies would support its position.

ix. American Pain Foundation (APF)

509. One of the societies with which Endo worked most closely was APF. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control (“NIPC”). Endo was one of APF’s biggest financial supporters, providing more than half of the \$10 million APF received from opioid manufacturers during its lifespan. Endo spent \$1.1 million on the NIPC program in 2008 alone, funding earmarked in part, for the creation of CME materials that were intended to be used repeatedly.

510. Endo’s influence over APF’s activities was so pervasive that APF President Will Rowe reached out to Defendants—including Endo—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Personnel from Defendants Purdue, Endo, Janssen, and Cephalon worked with Rowe to formulate APF’s response which was ultimately published.

511. Documents also indicate that Endo personnel were given advance notice of the materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July of 2009, APF’s Director of Strategic Development wrote to Endo personnel to give them advance notice of content that APF planned to be “putting . . . up on the website but it’s not up yet.” The Endo

employee assured the sender that she “w[ould] not forward it to anyone at all” and promised that she would “double delete it’ from [her] inbox.” In response, APF’s Director of Strategic Development replied internally with only four words: “And where’s the money?”

512. At no time was Endo’s relationship with APF closer than during its sponsorship of the National Initiative on Pain Control (“NIPC”). Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services which the Accreditation Council for Continuing Medical Education determined to be a “commercial interest” and could no longer serve as a sponsor. In response, Endo reached out to APF. An August 2009 document titled “A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control,” pointed out that “[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc.” According to this document, APF’s sponsorship of the NIPC “[o]ffers the APF a likely opportunity to generate new revenue, as Endo has earmarked substantial funding: \$1.2 million in net revenue for 2010 to continue the NIPC.” Further, sponsorship of the APF would “[p]rovide[] numerous synergies to disseminate patient education materials,” including “[h]andouts to attendees at all live events to encourage physicians to drive their patients to a trusted source for pain education—the APF website.”

513. A September 14, 2009 presentation to APF’s board contained a materially similar discussion of NIPC sponsorship, emphasizing the financial benefit to APF from assuming the role of administering NIPC. The proposal

“offer[ed] a solution to continue the development and implementation of the NIPC initiative as non-certified . . . yet independent education to physicians and healthcare professionals in the primary care setting, while providing the APF with a dependable, ongoing source of grant revenue.” A number of benefits related to NIPC sponsorship were listed, but chief among them was “a likely opportunity [for APF] to generate new revenue, as Endo has earmarked substantial funding: \$1.2 million in net revenue for 2010 to continue the NIPC.”

514. Internal Endo scheduling documents indicate that “NIPC module curriculum development, web posting, and live regional interactive workshops” were Endo promotional tasks in 2010. Endo emails indicate that Endo personnel reviewed the content created by NIPC and provided feedback.

515. Behind the scenes, Endo exercised substantial control over NIPC’s work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in the distribution of NIPC and APF materials, which in effect determined which messages were actually delivered to prescribers and consumers. As described below, Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

516. From 2007 until at least 2011, Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo’s commercial interest in, and access to, NIPC’s reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, Painknowledge.com. Endo not only

knew how many people viewed NIPC's content, but what their backgrounds were (e.g., primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

517. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. Endo's 2008 to 2012 Opana Brand Tactical Plan indicates that it sought to reach 1,000 prescribers in 2008 through live NIPC events, and also to "[l]everage live programs via enduring materials and web posting." Endo also planned to disseminate NIPC's work by distributing two accredited newsletters to 60,000 doctors nationwide for continuing education credit and by sponsoring a series of 18 NIPC regional case-based interactive workshops. Endo had earmarked more than one million dollars for NIPC activities in 2008 alone.

518. In short, NIPC was a key piece of Endo's marketing strategy. Indeed, internal APF emails question whether it was worthwhile for APF to continue operating NIPC given that NIPC's work was producing far more financial benefits for Endo than for APF. Specifically, after Endo approved a \$244,337.40 grant request to APF to fund a series of NIPC eNewsletters, APF personnel viewed it as "[g]reat news," but cautioned that "the more I think about this whole thing, [Endo's] making a lot of money on this with still pretty slender margins on [APF's] end."

APF's commitment to NIPC's "educational" mission did not figure at all in APF's consideration of the value of its work, nor was Endo's motive or benefit in doubt.

519. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" sponsored by Endo. These newsletters were edited by KOL Dr. Fine and listed several industry-backed KOLs, including Dr. Webster, as individual authors. Endo estimated that roughly 60,000 prescribers viewed each one. These CMEs were available to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors. Before-and-after surveys, summarized in the chart below, showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic	Comfort level <u>prior</u> to reading the article	Comfort level <u>after</u> reading the article
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimize Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies Into the Opioid Treatment Plan	42%	85%
Addressing Patients' Concerns Associated With Chronic Pain Treatment and Opioid Use	62%	92%
Opioid Therapy in Patients With a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an "Exit Strategy"	37%	90%

520. Endo documents made it clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, Endo

personnel directed that, when giving Endo-sponsored talks, NIPC faculty would not appear to be “Endo Speakers.” Nevertheless, the two parties understood that Endo and NIPC shared a common “mission to educate physicians” and working “through the APF . . . [wa]s a great way to work out . . . problems that could have been there without the APF’s participation and support.”

521. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have “possibly less potential for abuse” in elderly patients than in younger patients, even though there was no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient’s dose by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” NIPC webcast these CMEs from its own website, where they were available to, and were intended to reach, prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

522. Working with NIPC enabled Endo to make a number of misleading statements through the NIPC’s website, *Painknowledge.com*. Endo tracked visitors

to *PainKnowledge.com* and used *Painknowledge.com* to broadcast notifications about additional NIPC programming that Endo helped to create.

523. APF made a grant request to Endo to create an online opioid “tool-kit” for NIPC and to promote NIPC’s website, *Painknowledge.com*. In so doing, APF made clear that it planned to disseminate Defendants’ misleading messaging. The grant request expressly indicated APF’s intent to make misleading claims about functionality, noting: “Some of these people [in chronic pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life.” Endo provided \$747,517 to fund the project.

524. True to APF’s word, *Painknowledge.com* misrepresented that opioid therapy for chronic pain would lead to improvements in patients’ ability to function. Specifically, in 2009 the website instructed patients and prescribers that, with opioids, a patient’s “level of function should improve” and that patients “may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse.”

525. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that “[p]eople who take opioids as prescribed usually do not become addicted.” *Painknowledge.com* did not stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

526. Endo was the sole funder of *Painknowledge.com*, and it continued to provide that funding despite being aware of the website's misleading contents.

527. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by Derek McGinnis." Derek McGinnis was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Derek McGinnis's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

528. *Exit Wounds* is a textbook example of by Derek McGinnis on the drug companies' behalf. The book misrepresented the functional benefits of opioids by stating that opioid medications "*increase* your level of functioning" (emphasis in original).

529. *Exit Wounds* also misrepresented that the risk of addiction associated with the use of opioids to treat chronic pain was low. It claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

530. Finally, *Exit Wounds* misrepresented the safety profile of using opioids to treat chronic pain by omitting key risks associated with their use. Specifically, it omitted warnings of the risk of interactions between opioids and benzodiazepines—

a warning sufficiently important to be included on Endo's FDA-required labels. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids—a particular risk for veterans.

531. As outlined above, Endo exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain. In addition, as outlined above, Derek McGinnis's work was being reviewed and approved by drug company representatives, motivating him to draft pro-opioid propaganda masquerading as science. Combined, these factors gave Endo considerable influence over the work of Derek McGinnis and over APF. Further, by paying to distribute *Exit Wounds*, Endo endorsed and approved its contents.

532. In addition to its involvement with APF, Endo worked closely with other third-party Front Groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, Endo in some instances used its sales force to directly distribute certain publications by these Front Groups and KOLs, making those publications "labeling" within the meaning of 21 C.F.R. § 1.3(a).

533. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Dr. Fishman."

534. Endo spent \$246,620 to help FSMB distribute *Responsible Opioid Prescribing*. Endo approved this book for distribution by its sales force. Based on the

uniform and nationwide character of Endo's marketing campaign, and the fact that Endo purchased these copies specifically to distribute them, these copies were distributed to physicians nationwide, including, it is believed, physicians that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors.

x. American Geriatric Society (AGS)

535. In December 2009, Endo also contracted with AGS to create a CME to promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a \$44,850 donation. These guidelines misleadingly claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," as the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)" when in reality, opioid therapy was only an appropriate treatment for a subset of those patients, as recognized by Endo's FDA-mandated labels.

536. AGS's grant request to Endo made explicit reference to the CME that Endo was funding. Endo thus knew full well what content it was paying to distribute and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether or not to invest in it. After having sponsored the AGS CME, Endo's internal documents indicate that Endo's pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

xi. American Academy of Pain Medicine (AAPM)

537. Endo also worked with AAPM, which it viewed internally as “Industry Friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

538. A talk written by Endo in 2009 and approved by Endo’s Medical Affairs Review Committee,¹⁰⁸ titled *The Role of Opana ER in the Management of Chronic Pain*, includes a slide titled *Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain*. That slide cites the AAPM/APS Guidelines, which contain a number of misstatements and omits their disclaimer regarding the lack of supporting evidence. This talk dangerously misrepresented to doctors the force and utility of the 2009 Guidelines. Furthermore, Endo’s internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

xii. Key opinion leaders and misleading science.

539. Endo also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

¹⁰⁸ Although they were given slightly different names by each Defendant, each Defendant employed a committee that could review and approve materials for distribution. These committees included representatives from all relevant departments within Defendants’ organizations, including the legal, compliance, medical affairs, and marketing departments. The task of these review committees was to scrutinize the marketing materials Defendants planned to distribute and to ensure that those materials were scientifically accurate and legally sound. Tellingly, these committees were called to review only materials that created a potential compliance issue for the company, an implicit recognition by defendants that they ultimately would be responsible for the content under review.

540. Endo’s 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). Endo sought to achieve that goal by providing “clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis,” and subsequently successfully had articles on this topic published.¹⁰⁹

541. In the years that followed, Endo sponsored articles authored by Endo consultants and Endo employees, which argued that the metabolic pathways utilized by Opana ER, compared with other opioids, were less likely to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, Endo directed its publication manager to reach out to a list of consultants conducting an ongoing Endo-funded study, to assess their willingness to respond to an article¹¹⁰ that Endo believed emphasized the risk of death from opioids, “without [] fair balance.”¹¹¹

¹⁰⁹ These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

¹¹⁰ Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 New Engl. J. Med. 1981 (2010), finding that opioid overdose deaths and opioid prescriptions both increased by roughly 10-fold from 1990 to 2007.

¹¹¹ Endo did manage to get a letter written by three of those researchers, which was not published.

542. Endo's reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans. A 2012 Opana ER slide deck for Endo's speakers bureaus—on which these recruited physician speakers were trained and to which they were required to adhere—misrepresented that the drug had low abuse potential and suggested that as many as one-quarter of the adult population could be candidates for opioid therapy. Although the FDA requires such speaker slide decks to reflect a “fair balance” of information on benefits and risks, Endo's slides reflected one-sided and deeply biased information. The presentation's 28 literature citations were largely to “data on file” with the company, posters, and research funded by, or otherwise connected to, Endo. Endo's speakers relayed the information in these slides to audiences that were unaware of the skewed science on which the information was based.

543. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnotes referenced in the document, which it cited to indicate “no gap” in scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it did so out of context. For example, it cited a 2008 review article on opioid efficacy for several claims, including that “treatment of chronic pain reduces pain and improves functionality,”

but it ignored the article's overall focus on the lack of consistent effectiveness of opioids in reducing pain and improving functional status.¹¹²

544. Notwithstanding Endo's reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness. Endo also cited a lack of "head-to-head data" as a barrier to greater share acquisition, and the "lack of differentiation data" as a challenge to addressing the "#1 Key Issue" of product differentiation. This acknowledged lack of support did not stop Endo from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or be addictive than other opioids.

545. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

546. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the

¹¹² Andrea M. Trescot et al., *Opioids in the management of non-cancer pain: an Update of American Society of the Interventional Pain Physicians*, Pain Physician 2008 Opioids Special Issue, 11:S5-S62.

opioid now, will it work later when I really need it?” and responded that “[t]he dose can be increased... [y]ou won’t ‘run out’ of pain relief.”

547. Dr. Portenoy received research support, consulting fees, and honoraria from Endo for editing *Understanding Your Pain* and other projects.

548. *Understanding Your Pain* was available on Endo’s website during the time period of this Complaint and was intended to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

549. Endo similarly distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”

550. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo’s efforts to “[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs.” The slide indicates that the book would be particularly effective “for [the] PCP audience” and instructed “[s]ales representatives [to] deliver [the book] to participating health care professionals.” The slide, shown below, demonstrates Endo’s express incorporation of this book by a KOL into its marketing strategy:

Opioid Abuse and Managing Pain Handbook

Objective:

- ◆ Provide value added educational offering

Description:

- ◆ Handbook provides educational resource, in particular for PCP audience
- ◆ Introduction of program via direct mail
- ◆ Sales representatives delivery to participating healthcare professionals

Timing:

- ◆ 1Q-3Q

Investment:

- ◆ \$350,000

Avoiding Opioid Abuse While Managing Pain
A Guide for Practitioners
by Lynn R. Webster, MD, and Beth Dove

Confidential – For Internal Use Only
DRAFT – Pending Management Approval

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Accelerating Our Growth

551. Endo Documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal Endo documents demonstrate that the book had been approved for distribution by Endo's sales force, and that Endo had fewer than 8,000 copies on hand in March of 2013. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach prescribers.

xiii. Endo's deceptive statements to prescribers and patients.

552. Endo also directed the dissemination of the misstatements described above to patients and prescribers through the media of its sales force, speakers bureaus, CMEs, and the *Painknowledge.com* website.

553. Because of the extensive, highly coordinated and uniform nature of Endo's marketing, it is believed that Endo's sales representatives consistent with

their training delivered all of these deceptive messages to prescribers that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors.

554. Endo also directed misleading marketing to prescribers and patients through the APF/NIPC materials it sponsored, reviewed, and approved. For example, Endo hired a New York-based KOL to deliver on April 27, 2010 a CME titled *Managing Persistent Pain in the Older Patient*. As described above, this CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients' ability to function. An email invitation to the event and other NIPC programs was sent to "all healthcare professionals" in APF's database, which it is believed included that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors.

555. The significant response to *Painknowledge.com* also indicates that those websites were viewed by prescribers who were exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids. As of September 14, 2010, *Painknowledge.com* had 10,426 registrants, 86,881 visits, 60,010 visitors, and 364,241 page views. Upon information and belief, based on the site's nationwide availability, among the site's visitors were patients and prescribers who were exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids.

556. Endo knew or had reason to know that harms from its deceptive marketing would be felt in nationwide, and in particular, by the claimants of

Plaintiff and other Workers' Compensation Payors. Indeed, Endo saw workers' compensation programs as a lucrative opportunity, and promoted the use of opioids for chronic pain arising from work-related injuries, like chronic lower back pain. Endo developed plans to "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees." In 2007, Endo planned to reach 5,000 workers' compensation carriers to ensure that Opana ER would be covered under disability insurance plans. Endo knew or should have known that claims for its opioids would be paid for by Workers' Compensation Payors.

D. Janssen

557. Janssen promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers' program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Janssen also conveyed other misrepresentations including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

558. Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional

improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

559. Based on the extensive and highly coordinated, uniform nature of Janssen's marketing, it is believed that Janssen conveyed these deceptive messages to prescribers that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors. The materials that Janssen generated in collaboration with third-parties also were distributed or made available with the intent that prescribers, including those who wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors would rely on them in choosing to use opioids to treat chronic pain.

i. Janssen's deceptive direct marketing.

560. Janssen joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than \$90 million on detailing.

561. Janssen's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, its Nucynta Business

Plans indicated that one of the “drivers” to sell more Nucynta among primary care physicians was the “[l]ow perceived addiction and/or abuse potential” associated with the drug. However, there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low.

Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but Janssen touted the ease with which patients could come off opioids.

ii. Janssen’s deceptive sales training.

562. Janssen’s sales force was compensated based on the number of Nucynta prescriptions written in each sales representative’s territory. Janssen encouraged these sales representatives to maximize sales of Nucynta and meet their sales targets by relying on the false and misleading statements described above.

563. For example, Janssen’s sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like Nucynta because of their fear of addicting patients, but this reluctance is unfounded because “the risks . . . are [actually] much smaller than commonly believed.” Janssen also encouraged its sales force to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A Janssen sales training PowerPoint titled “Selling Nucynta ER and Nucynta” indicates that the “low incidence of opioid withdrawal symptoms” is a “core message” for its sales force. The message was touted at Janssen’s Pain District Hub Meetings, in which Janssen periodically gathered its sales force personnel to discuss sales strategy.

564. This “core message” of a lack of withdrawal symptoms runs throughout Janssen’s sales training materials. For example, Janssen’s “Licensed to Sell” Facilitator’s Guide instructs those conducting Janssen sales trainings to evaluate trainees, in part, on whether they remembered that “[w]ithdrawal symptoms after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively” and whether they were able to “accurately convey” this “core message.” Janssen further claimed in 2008 that “low incidence of opioid withdrawal symptoms” was an advantage of the tapentadol molecule.

565. Similarly, a Nucynta Clinical Studies Facilitator’s Guide instructs individuals training Janssen’s sales representatives to ask trainees to describe a “key point”—that “83% of patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy”—“as though he/she is discussing it with a physician.”

566. This misrepresentation regarding withdrawal was one of the key messages Janssen imparted to employees in the “Retail ST 101 Training” delivered to Nucynta sales representatives.

567. Indeed, training modules between 2009 and 2011 instruct training attendees that “most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms” and “[n]o patients experienced moderately severe or severe withdrawal symptoms.”

568. During the very time Janssen was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Nucynta to treat chronic pain, it knew or should have known, that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction. Janssen knew or should have known that its studies on withdrawal were flawed and created a misleading impression of the rate of withdrawal symptoms and, as a result, the risk of addiction.

569. The misleading messages and materials Janssen provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and due to the extensive, highly coordinated and uniform nature of Janssen's marketing it is believed reached prescribers that wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors in a number of ways, including through its sales force in detailing visits, as well as through websites and ads. They were also delivered to prescribers by Janssen's paid speakers, who were required by Janssen policy and by FDA regulations to stay true to Janssen's nationwide messaging.

iii. Janssen's deceptive speakers bureau programs.

570. Janssen did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

571. Janssen’s speakers worked from slide decks—which they were required to present—that contained the deceptive information about the risks, benefits, and superiority of opioids outlined above. For example, a March 2011 speaker’s presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that “more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms.”

572. An August 2011 speaker presentation titled *New Perspectives in the Management of Moderate to Severe Chronic Pain* contained the same misleading discussion of the risks associated with chronic opioid therapy. It similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER “abruptly without initiating alternative opioid therapy” reported no withdrawal symptoms whatsoever. The same deceptive claims regarding risks of adverse events and withdrawal appeared in a July 2012 speaker’s presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models*.

573. These speakers' presentations were part of Janssen's nationwide marketing efforts. Upon information and belief, a number of these events were available to and were intended to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

iv. Janssen's deceptive unbranded advertising.

574. Janssen was aware that its branded advertisements and speakers' programs would face regulatory scrutiny that would not apply to its unbranded materials, so Janssen also engaged in direct, unbranded marketing.

575. One such unbranded project was Janssen's creation and maintenance of *Prescriberresponsibly.com*, a website aimed at prescribers and patients that claims that concerns about opioid addiction are "overstated." A disclaimer at the bottom of the website states that the "site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content." This website was available to and intended to reach prescribers and claimants of Plaintiff and the Workers' Compensation Payors.

v. Janssen's deceptive third-party statements.

576. Janssen's efforts were not limited to directly making misrepresentations through its sales force, speakers' bureau, and website. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, Janssen obscured its involvement in certain marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

577. Janssen worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). In doing so, Janssen contracted with a medical publishing firm, Conrad & Associates, LLC. The content was drafted by a writer (“Medical Writer X”) hired by Conrad & Associates and funded by Janssen. These materials were reviewed, in detail, by Janssen’s medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

578. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Janssen, the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain. He knew that the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. Medical Writer X knew of the drug company’s sponsorship of the publication, and he would go to the company’s website to learn about the drug being promoted. He also knew that his clients—including Janssen—would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe and the risk of addiction is low; (b) opioids are effective for chronic pain; and (c) opioids are under-prescribed because doctors are hesitant, confused, or face other barriers.

579. *Finding Relief* is rife with the deceptive content: it misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The

guide states as a “fact” that “opioids may make it *easier* for people to live normally” (emphasis in the original). The functional claims contained in *Finding Relief* are textbook examples of Defendants’ use of third parties to disseminate messages the FDA would not allow them to say themselves. Compare, e.g.:

Branded Advertisement That Triggers FDA Warning Letter (2008) ¹¹³	Seemingly Independent Publication: “Finding Relief: Pain Management for Older Adults” (Final Authority, Janssen 2009)
<ul style="list-style-type: none"> Improvement in Daily Activities Includes: Walking on a flat surface Standing or sitting Climbing stairs Getting in and out of bed or bath Ability to perform domestic duties 	<ul style="list-style-type: none"> Your recovery will be measured by how well you reach functional goals such as Sleeping without waking from pain Walking more, or with less pain Climbing stairs with less pain Returning to work Enjoying recreational activities Having sex Sleeping in your own bed

580. *Finding Relief* also trivialized the risks of addiction describing as a “myth” that opioids are addictive and asserting as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”

581. *Finding Relief* further misrepresented that opioids were safe at high doses by listing dose limitations as “disadvantages” of other pain medicines and omitting any discussion of risks from increased doses of opioids. The publication

¹¹³ This advertisement drew an FDA Warning Letter dated March 24, 2008. Though the advertisement was by drug company King, it is used here to demonstrate the types of claims that the FDA regarded as unsupported.

also falsely claimed that it is a “myth” that “opioid doses have to be bigger over time.”

582. Finally, *Finding Relief* deceptively overstated the risks associated with alternative forms of treatment. It juxtaposed the advantages and disadvantages of NSAIDs on one page, with the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “increase[d] . . . risk of heart attack and stroke.” Conversely, the only adverse effects of opioids listed by *Finding Relief* are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

583. Janssen was not merely a passive sponsor of *Finding Relief*. Instead, Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. A “Copy Review Approval Form” dated October 22, 2008 indicates that key personnel from Janssen’s Advertising & Promotion, Legal, Health Care Compliance, Medical Affairs, Medical Communications, and Regulatory Departments reviewed and approved *Finding Relief*. All six Janssen personnel approving the publication checked the box on the approval form indicating that *Finding Relief* was “Approved With Changes.” After the publication was modified at the behest of Janssen personnel, Janssen paid to have its sales force distribute 50,000 copies of *Finding Relief* throughout the nation. Thus,

Finding Relief is considered labeling for Janssen’s opioids within the meaning of 21 C.F.R. § 1.3(a).

584. AAPM purchased and distributed copies of *Finding Relief* to all of its members.

vi. AGS – misleading medical education.

585. Janssen also worked with AGS on another project—AGS’s CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claimed that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse” although the study supporting this assertion did not analyze addiction rates by age. They also stated falsely, that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation).” Based on Janssen’s control over AGS’s *Finding Relief*, Janssen also would have exercised control over this project as well.

vii. American Pain Foundation (APF)

586. Janssen also worked with APF to carry out its deceptive marketing campaign. Documents obtained from one of Janssen’s public relations firms, Ketchum, indicate that Janssen and the firm enlisted APF as part of an effort to “draft media materials and execute [a] launch plan” for Janssen’s drugs at an upcoming meeting of the AAPM. Janssen also drew on APF publications to corroborate claims in its own marketing materials and its sales training. Janssen personnel participated in a March 2011 call with APF’s “Corporate Roundtable,” in which they worked with APF and drug company personnel to develop strategies to

promote chronic opioid therapy. APF personnel spoke with Janssen employees who “shar[ed] expertise from within their company for [a] public awareness campaign.”

587. Their joint work on the “Corporate Roundtable” demonstrates the close collaboration between Janssen and APF in promoting opioids for the treatment of chronic pain. APF President Will Rowe also reached out to Defendants—including Janssen— rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Additional examples of APF’s collaboration with Janssen are laid out below.

588. Prominent among these efforts was the *Let’s Talk Pain* website. Janssen sponsored *Let’s Talk Pain* in 2009, acting in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing. Janssen financed and orchestrated the participation of these groups in the website.

589. Janssen exercised substantial control over the content of the *Let’s Talk Pain* website. Janssen’s internal communications always referred to *Let’s Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER. Janssen regarded *Let’s Talk Pain* and another website—*Prescriberesponsibly.com*— as integral parts of Nucynta’s launch:

PR/Communication Plan for NUCYNTA ER

UNMET NEEDS


PAIN LEADERSHIP

DIFFERENTIATE

STRONG EFFICACY AND FAVOURABLE GI TOLERABILITY PROFILE

BRANDED

- Promote clinical evidence for NUCYNTA ER with data-driven press releases (Q2-Q4)
- PDUFA Date with various media using KOLs (Top-tier media, Social media) (Q3)




- Art exhibit featuring art from chronic pain patients at HCP-focused PAINWeek(Sep)
- Other (Blogger briefing in Q3, Testimonial of chronic pain patients, Online media briefing on pain management)

UNBRANDED

- Smart Moves, Smart choices
- Prescribe responsibly
- Let's talk Pain

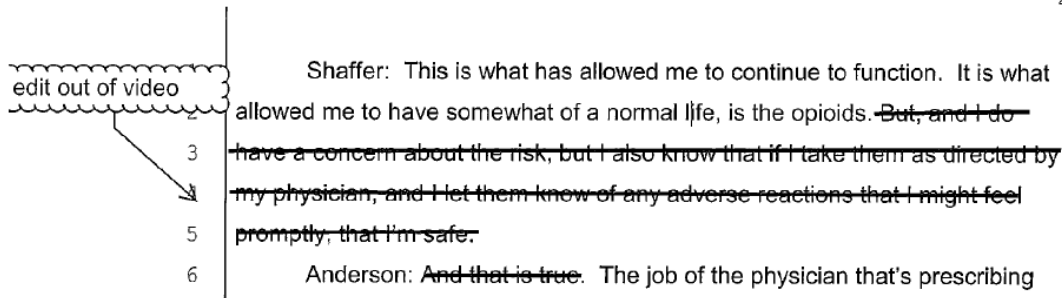




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590. Janssen documents also reveal that Janssen personnel viewed APF and AAPM as “coalition members” in the fight to increase market share.

591. To this end, Janssen and APF entered into a partnership to “keep pain and the importance of responsible pain management top of mind” among prescribers and patients. They agreed to work to reach “target audiences” that included patients, pain management physicians, primary care physicians, and KOLs. One of the roles Janssen assumed in the process was to “[r]eview, provide counsel on, and approve materials.” Janssen did in fact review and approve material for the *Let's Talk Pain* website, as evidenced by the following edits by a Janssen executive to the transcript of a video that was to appear on the site:



592. The final version of the video on *Let's Talk Pain* omitted the stricken language above.

593. This review and approval authority extended to the *Let's Talk Pain* website. Emails between Janssen personnel and a consultant indicate that, even though the *Let's Talk Pain* website was hosted by APF, Janssen had approval rights over its content. Moreover, emails describing Janssen's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions."

594. As a 2009 Janssen memo conceded, "[t]he *Let's Talk Pain Coalition* is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara **maintain editorial control of all *Let's Talk Pain* materials and publications**" (emphasis added).

595. A 2011 Consulting Agreement between Janssen and one of APF's employees, relating to the dissemination of national survey data, demonstrates the near-total control Janssen was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including requiring APF to circulate and post Janssen's promotional content. The agreement required APF to "participate in status calls between Janssen, APF, AAPM, ASPMN, and Ketchum as requested by Janssen"

and required APF to “respond to requests to schedule status calls **within 48 hours** of the request” (emphasis in original). APF also was required to “[r]eview and provide feedback to media materials, including a press release, pitch email, a key messages document, and social media messages, **within one week** of receipt” (emphasis in original).

596. The agreement further required APF to provide a summary of the survey results in APF’s PAIN MONITOR e-newsletter, post a link to the survey results on APF’s Facebook page, send out tweets related to the survey, serve as a spokesperson available for media interviews, “[s]hare information with any media contacts with whom APF has existing relationships to promote the announcement of the national survey findings,” identify at least two patient spokespersons to talk about the survey data, and include the survey results in “any future APF materials, as appropriate.” Tellingly, “any ideas made or conceived by [APF] in connection with or during the performance” of the Agreement “shall be the property of, and belong to, [Janssen].”

597. Janssen also exercised its control over *Let’s Talk Pain*. Janssen was able to update the *Let’s Talk Pain* website to describe its corporate restructuring and Janssen personnel asserted their control over “video additions” by reviewing and editing the interview touting the functional benefits of opioids. Given its

editorial control over the content of *Let's Talk Pain*, Janssen was, at all times, fully aware of—and fully involved in shaping—the website's content.¹¹⁴

598. *Let's Talk Pain* contained a number of misrepresentations.

599. For example, *Let's Talk Pain* misrepresented that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality. *Let's Talk Pain* featured an interview claiming that opioids were what allowed a patient to “continue to function.”

600. In 2009, *Let's Talk Pain* also promoted the concept of “pseudoaddiction,” which it described as patient behaviors that may occur when pain is under-treated” but differs “from true addiction because such behaviors can be resolved with effective pain management” (emphasis added). *Let's Talk Pain* was available to, and was intended to, reach patients and prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

601. Janssen also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by “Medical Writer X.” It is fully representative of his work on behalf of drug companies.

¹¹⁴ It bears noting that Janssen does not publicly identify its role in creating *Let's Talk Pain's* content. Instead, *Let's Talk Pain* represents that “coalition members” develop the content that appears on the website and lists Janssen as the only sponsor of that coalition.

602. Janssen gave APF substantial assistance in distributing *Exit Wounds* throughout the nation by providing grant money and other resources.

viii. Janssen’s deceptive statements to prescribers and patients.

603. Janssen also directed the misstatements described above through CMEs, its sales force and recruited physician speakers to patients and to prescribers, including, it is believed, those who wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

604. Janssen sponsored CMEs and talks were attended by large numbers of prescribers, including, it is believed, those who wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

605. The experiences of specific prescribers who attended confirm both that Janssen’s national marketing campaign included the misrepresentations, and that the company disseminated these same misrepresentations to prescribers who often wrote opioid prescriptions. In particular, prescriber accounts of presentations reflect that Janssen detailers claimed that Nucynta was “not an opioid” because it worked on an “alternate receptor”;¹¹⁵ claimed that Janssen’s drugs would be less problematic for patients because they had anti-abuse properties and were “steady state”; claimed that patients on Janssen’s drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied

¹¹⁵ The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as an “opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit.”

that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

E. Purdue

606. Purdue promoted its branded opioids—principally, Oxycontin, Butrans, and Hysingla—and opioids generally in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Purdue did this through its sales force, branded advertisements, promotional materials, and speakers, as well as a host of materials produced by its third-party partners, most prominently APF. Purdue’s sales representatives and advertising also misleadingly implied that OxyContin provides a full 12 hours of pain relief, and its allied Front Groups and KOLs conveyed the additional deceptive messages about opioids’ safety at higher doses, the safety of alternative therapies, and the effectiveness of addiction screening tools.

607. Based on the extensive and highly coordinated, uniform nature of Purdue’s marketing, it is believed that Purdue conveyed these deceptive messages to prescribers that wrote opioid prescriptions paid for by Plaintiff and other Workers’ Compensation Payors. Purdue distributed these messages or facilitated their distribution with the intent that prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

i. Purdue’s deceptive marketing.

608. Purdue directly disseminated deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of

opioids to treat chronic pain. Purdue directed these messages to prescribers and consumers through its sales force and branded advertisements.

609. Purdue engaged in in-person marketing to doctors that prescribed opioids to claimants of Plaintiff and the Workers' Compensation Payors. Purdue had 250 sales representatives in 2007, of whom 150 were devoted to promoting sales of OxyContin full time. Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.¹¹⁶ Indeed, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines, which as discussed above deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories, with doctors during individual sales visits.

610. Purdue's spending on detailing reached its nadir in 2006 and 2007, as the company faced civil and criminal charges for misbranding OxyContin. Since settling those charges in 2007, however, Purdue has sharply increased its quarterly spending on promotion through its sales force, from under \$5 million in 2007 to more than \$30 million by the end of 2014.

¹¹⁶ Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

611. Purdue also marketed its drugs through branded advertisements which relied on, among other deceptive tactics, misleading statements about the efficacy and onset of OxyContin. Purdue marketed its drug as effective for 12 hours while knowing that these claims were misleading because, for many patients, the pain relief lasted for as little as eight hours, leading to end-of-dose failure and withdrawal symptoms. This prompted doctors to prescribe, or patients to take, higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

612. For example, a “Conversion and Titration Guide” submitted to the FDA and distributed to physicians by Purdue, prominently referred to “Q12h OxyContin Tablets,” meaning that each tablet was intended to “offer . . . every-twelve-hour dosing.” Other marketing materials directed at physicians and disseminated across the country in 2006 touted that OxyContin’s “12-hour AcroContin Delivery System” was “designed to deliver oxycodone over 12 hours,” which offered patients “life with Q12H relief.” Those same marketing materials included a timeline graphic with little white paper pill cups at “8AM” and, further down the line, at “8PM” only. They also proclaimed that OxyContin provided “Consistent Plasma Levels Over 12 Hours” and set forth charts demonstrating absorption measured on a logarithmic scale, which fraudulently made it appear that levels of oxycodone in the bloodstream slowly taper over a 12-hour time period.

613. Purdue advertisements that ran in 2005 and 2006 issues of the *Journal of Pain* depicted a sample prescription for OxyContin with “Q12h” handwritten.

Another advertisement Purdue ran in 2005 in the *Journal of Pain* touted OxyContin's "Q12h dosing convenience" and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 *Clinical Journal of Pain*.

614. Purdue continued to include prominent 12-hour dosing instructions in its branded advertising, such as in a 2012 Conversion and Titration Guide, which states: "Because each patient's treatment is personal / Individualize the dose / Q12h OxyContin Tablets."

615. As outlined above, however, these statements are misleading because they fail to make clear that a 12-hour dose does not equate to 12 hours of pain relief. Nevertheless, Purdue's direct marketing materials have misleadingly claimed OxyContin offers 12-hour "dosing convenience."

616. As described below, these deceptive statements regarding the efficacy of OxyContin were made to prescribers and claimants.

617. Purdue's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

618. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and

the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients’ lives and ability to function and that there was substantial evidence to the contrary.

619. Some of the greatest weapons in Purdue’s arsenal, however, were unbranded materials it directly funded and authored. These were in addition to the unbranded materials, described below, that Purdue channeled through third parties.

620. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence—of addiction. However, Purdue knew, as described above, that OxyContin was used non-medically by injection less than less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as “Indications of Possible Drug Abuse”—downplaying much more prevalent signs of addiction associated with OxyContin use such as asking for early refills, making it seem as if addiction only occurs when opioids are taken illicitly.

621. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of “pseudoaddiction” rather than addiction itself. Specifically, it noted that the concept of “pseudoaddiction” had “emerged in the literature” to describe “[drug-seeking behaviors] in patients who have pain that has not been effectively

treated.” Nowhere in *Providing Relief, Preventing Abuse* did Purdue disclose the lack of scientific evidence justifying the concept of “pseudoaddiction,” or that the phrase itself had been coined by a Purdue vice president.

622. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach prescribers that wrote opioids prescriptions paid for by Plaintiff and the Workers’ Compensation Payors. As described below, the deceptive statements in *Providing Relief, Preventing Abuse* regarding addiction were the very same messages Purdue directed at such prescribers through its sales force.

623. Purdue also disseminated misrepresentations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

624. Consistent with Purdue’s efforts to portray opioid treatment as “essential” for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an “inadequate understanding” that leads to “inadequate pain control,” *In the Face of Pain* criticized policies that limited access to opioids as being “at odds with best medical practices” and encouraged patients to be “persistent” in finding doctors who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids.

625. *In the Face of Pain* was available nationally and was intended to reach prescribers, including it believed, those that wrote opioid prescriptions paid for by Plaintiff and other Workers’ Compensation Payors.

626. Purdue also used its unbranded website *Partners Against Pain* to promote the same deceptive messages regarding risk of addiction and delivered by its sales representatives. On this website, Purdue posted *Clinical Issues in Opioid Prescribing*, a pamphlet that was copyrighted in 2005. Purdue also distributed a hard-copy version of this pamphlet. *Clinical Issues in Opioid Prescribing* claimed that “illicit drug use and deception” were not indicia of addiction, but rather indications that a patient’s pain was undertreated. The publication indicated that “[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.” In other words, Purdue suggested that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids—turning evidence of addiction into an excuse to sell and prescribe even more drugs.

627. Purdue’s misleading messages and materials were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and in a number of ways reached prescribers that wrote opioid prescriptions, including, it is believed, those who prescribed opiates for claimants of Plaintiff and other Workers’ Compensation Payors. For example, they were delivered by Purdue’s sales representatives during detailing visits as well as made available to claimants and prescribers through websites and ads, including ads in prominent medical journals. They would have also been delivered to prescribers by Purdue’s paid

speakers, who were required by Purdue policy and by FDA regulations to stay true to Purdue's nationwide messaging.

ii. Purdue's deceptive third-party statements.

628. Purdue's efforts were not limited to making misrepresentations through its own sales force and its own branded and unbranded marketing materials. As described above, Purdue knew that regulatory constraints restricted what it could say about its drugs through direct marketing. For this reason, like the other Defendants, Purdue enlisted the help of third parties to release misleading information about opioids. The most prominent of these was APF.

629. Purdue exercised considerable control over APF, which published and disseminated many of the most blatant falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, is described in detail below.

630. Purdue exercised its dominance over APF over many projects and years. Purdue was APF's second-biggest donor, with donations totaling \$1.7 million. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help

promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

631. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason. This agreement demonstrates APF’s lack of independence and its willingness to surrender to Purdue’s control and commercial interests, which would have carried across all of APF’s work.

632. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright.

633. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated

with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant \$7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to “to discuss and rehearse the delivery of [Purdue’s] campaign messages” and Purdue committed that “[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call.” At all times, decisions regarding the final content on the *Partners Against Pain* website were “at the sole discretion of Purdue.”

634. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson for the launch of one of Purdue’s opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF’s paid employee, Mickie Brown. The consultant’s services would be provided in return for a \$10,000 consulting fee for APF and \$1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue. It was not until later that APF worried about “how Purdue sees this program fitting in with our [existing] grant request.”

635. Given the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue’s control at all relevant times with respect to *Partners Against Pain*.

636. APF acquiesced to Purdue's frequent requests that APF provide "patient representatives" for *Partners against Pain*. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on *Inthefaceofpain.com* as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain in which, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

637. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648-page views between March 2014 and March 2015. With the exception of one document linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of \$231,000 for their participation in speakers' programs, advisory meetings and travel costs between 2008 and 2013. The New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers.

638. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). PCF was run not by APF, but by Defendant

Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Rosen exercised full control of PCF, telling them "what to do and how to do it." This control allowed him, in turn, to run APF as, in accordance with Rosen's thinking, "PCF was APF, which was Purdue." PCF meets regularly in-person and via teleconference, and shares information through an email listserv.

639. In 2011, APF and another third-party advocacy group, the Center for Practical Bioethics, were considering working together on a project. Having reviewed a draft document provided by the Center for Practical Bioethics, the APF employee cautioned that "this effort will be in cooperation with the efforts of the PCF" and acknowledged that "I know you have reservations about the PCF and pharma involvement, but I do believe working with them and keeping the lines of communications open is important." The Center for Practical Bioethics CEO responded by indicating some confusion about whom to speak with, asking "[i]s Burt Rosen the official leader" and reflecting what other sources have confirmed.

640. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Alpharma, and Front Groups APF and ACPA (self-described as "industry-funded" groups), developed a plan to address a perceived "lack of coordination" among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop simplified "key" messages" to use for public education purposes. Their messages were reflected in programs like NIPC's *Let's Talk Pain* (put together by Endo and APF), and Purdue's *In the Face of Pain*.

641. When the FDA required drug companies to fund CMEs related to opioid risks in accordance with its 2009 REMS, Purdue, along with these Front Groups, worked through the PCF to ensure that, although it was mandatory for drug companies to fund these CMEs, it would not be mandatory for prescribers to attend them. A survey was circulated among Defendants Endo, Janssen, and Purdue, which predicted that the rates of doctors who would prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required in accordance with the REMS. With a push from PCF, acting under Purdue's direction, the CMEs were not made mandatory for prescribers.

642. APF showed its indebtedness to Purdue and its willingness to serve Purdue's corporate agenda when APF chairman Dr. James N. Campbell testified on the company's behalf at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement."¹¹⁷ Despite its ostensible role as a patient advocacy organization, APF was willing to overlook substantial evidence that Purdue blatantly, despite its clear knowledge to the contrary, told physicians and patients that OxyContin was "rarely" addictive and less addictive than other opioids. Like Purdue, APF ignored the truth about

¹¹⁷ *Evaluating the Propriety and Adequacy of the Oxycontin Criminal Settlement: Before the S. Comm. On the Judiciary*, 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Purdue was also able to exert control over APF through its relationships with APF's leadership. Purdue-sponsored KOLs Russell Portenoy and Scott Fishman chaired APF's board. Another APF board member, Perry Fine, also received consulting fees from Purdue. APF board member Lisa Weiss was an employee of a public relations firm that worked for both Purdue and APF. Weiss, in her dual capacity, helped vet the content of the Purdue-sponsored *Policymaker's Guide*, which is described herein.

opioids and parroted Purdue's deceptive messaging. Dr. Campbell testified on Purdue's behalf that addiction was a "rare problem" for chronic pain patients and asserted: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug." There was, and is, no scientific support for those statements.

643. APF President Will Rowe reached out to Defendants—including Purdue—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine.

644. Purdue's control over APF shaped, and is demonstrated by specific APF, pro-opioid publications. These publications had no basis in science and were driven (and can only be explained) by the commercial interest of pharmaceutical companies—Purdue chief among them.

645. Purdue provided significant funding to and was involved with APF's creation and dissemination of *A Policymaker's Guide to Understanding Pain & Its Management*, originally published in 2011. *A Policymaker's Guide to Understanding Pain & Its Management* misrepresented that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

646. Specifically, *A Policymaker's Guide to Understanding Pain & Its Management* claimed that “multiple clinical studies” demonstrated that “opioids . . . are effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain” and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the safety of opioids long-term and noted that “[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids.”¹¹⁸

647. The *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that pain had generally been “undertreated” due to “[m]isconceptions about opioid addiction” and that “less than 1% of children treated with opioids become addicted.”

648. Moreover, the *Policymaker's Guide* attempted to distract doctors from their patients' drug-seeking behavior by labeling it as “pseudoaddiction,” which, according to the guide, “describes patient behaviors that may occur when pain is undertreated.” Like *Partners Against Pain*, *A Policymaker's Guide* noted that “[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.” The similarity between these messages

¹¹⁸ Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

regarding “pseudoaddiction” highlights the common, concerted effort behind Purdue’s and its co-Defendants’ deceptive statements.

649. The *Policymaker’s Guide* further misrepresented the safety of increasing doses of opioids and deceptively minimized the risk of withdrawal. For example, the *Policymaker’s Guide* claimed that “[s]ymptoms of physical dependence” on opioids in long-term patients “can often be ameliorated by gradually decreasing the dose of medication during discontinuation” while omitting the significant hardship that often accompanies cessation of use. Similarly, the *Policymaker’s Guide* taught that even indefinite dose escalations are “sometimes necessary” to reach adequate levels of pain relief while completely omitting the safety risks associated with increased doses.

650. Purdue provided substantial monetary assistance toward the creation and dissemination of the *Policymaker’s Guide*, providing APF with \$26,000 in grant money. APF ultimately disseminated *Policymaker’s Guide* on behalf of Defendants, including Purdue. Purdue was not only kept abreast of the content of the guide as it was being developed, but, based on the periodic reports APF provided to Purdue regarding its progress on the *Policymaker’s Guide*, had editorial input of the contents.

651. The *Policymaker’s Guide* was posted online and was available to and intended to reach prescribers and claimants, including those who wrote opioid prescriptions paid for by Plaintiff and other Workers’ Compensation Payors.

652. Purdue's partnership with APF did not end with the *Policymaker's Guide*. Purdue also substantially assisted APF by sponsoring *Treatment Options: A Guide for People Living with Pain*, starting in 2007. Based on Purdue's control of other APF projects, Purdue also would have exercised control over *Treatment Options*.

653. *Treatment Options* is rife with misrepresentations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresents that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve."

654. Further, as outlined above, *Treatment Options* claims that addiction is rare and that, when it does occur, it involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, painting a narrow and misleading portrait of opioid addiction.

655. *Treatment Options* also promotes the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses and inflates the number of deaths associated with NSAID use, distinguishing opioids as having less risk. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose." This lack of ceiling is considered to be beneficial as some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options* warns that the risks associated with

NSAID use increased if NSAIDs are “taken for more than a period of months,” but deceptively omits any similar warning about the risks associated with the long-term use of opioids.

656. *Treatment Options* was posted online and remains online today. It was available to and intended to reach prescribers and patients.

657. Purdue also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

658. Purdue provided APF with substantial assistance in distributing *Exit Wounds* in throughout the nation by providing grant money and other resources.

iii. Purdue’s work with other third-party Front Groups and KOLs.

659. Purdue also provided other third-party Front Groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

660. In 2007, Purdue sponsored FSMB’s *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by Dr. Scott Fishman.

661. Purdue spent \$150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally and was available to and intended

to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

662. Along with Janssen, Purdue worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As discussed above, these guidelines falsely claimed that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse” as the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that “[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendation).”

663. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines' development could lead to allegations of bias and “the appearance of conflict.” Accordingly, AGS endeavored to eliminate “the root cause of that flack” by turning down commercial support to produce the 2009 Guidelines. Having determined that its veneer of independence would be tarnished if it accepted drug company money to create the content, AGS decided to develop the guidelines itself and turn to the drug companies for funding to *distribute* the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS's “strategy that we will take commercial support to disseminate [the 2009 Guidelines] if such support is forthcoming.” AGS knew that it would be difficult to find such support unless the report was viewed favorably by opioid makers.

664. AGS sought and obtained grants from Endo and Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons*. As a result, the publication was distributed nationally, and was available to and was intended to reach prescribers that wrote opioid prescriptions including those, it is believed, who wrote prescriptions for claimants of Plaintiff and other Workers' Compensation Payors. Indeed, internal documents of another Defendant, Endo, relate reports that pharmaceutical sales representatives employed by Purdue discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.¹¹⁹

665. Purdue sponsored a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME was presented at various locations in the United States.

666. Purdue also sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation also deceptively instructed prescribers that screening tools, patient agreements, and urine test prevented "overuse of prescriptions" and "overdose

¹¹⁹ As described above, Purdue also provided substantial support for the AAPM/APS guidelines. The 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Defendants Janssen, Cephalon, Endo, and Purdue.

deaths.” At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster’s Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to reach prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers’ Compensation Payors.

667. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* was devoted entirely to the message of treating chronic pain with opioids. Although the program purported to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing.

668. This “educational” program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, only discussing treatment of chronic pain with opioids.

669. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient’s early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as “pseudoaddiction,” the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor in the role-play treats this patient by prescribing a high-dose,

long-acting opioid. This CME was available online and was intended to reach prescribers that wrote opioid prescriptions including those, it is believed, who wrote prescriptions paid for by Plaintiff and other Workers' Compensation Payors.

670. Purdue also sponsored a CME titled *Overview of Management Options* issued by the American Medical Association in 2003, 2007, and 2013. The CME was edited by KOL Russel Portenoy, among others. It deceptively instructs physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In reality, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online in the United States and was available to prescribers that wrote opioid prescriptions paid for by Plaintiff and the Workers' Compensation Payors.

iv. Purdue's work with other third-party Front Groups and KOLs.

671. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.¹²⁰ Purdue had these articles placed in headache-specific journals where

¹²⁰ Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone*

they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times; the second does not even appear on Google Scholar. Five years later, Purdue funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding the fact that that Purdue-funded studies, testing Purdue's own drugs, had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive. This article was placed in a prominent pain journal and has been cited hundreds of times.¹²¹

672. Purdue directed the dissemination of the misstatements described above to claimants and prescribers through the Front Groups, KOLs, and publications described above, as well as through its sales force and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the benefits of Purdue's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

673. Purdue's deceptive message that OxyContin provided 12 hours of pain relief was also carried directly into the offices of doctors for claimants by Purdue's

CR, a Long-Acting Opioid, for Severe Chronic Daily Headache, 19 Headache Q. 305 (1999).

¹²¹ C. Peter N. Watson et al., *Controlled-release Oxycodone Relieves Neuropathic Pain: a Randomized Controlled Trial in Painful Diabetic Neuropathy*, 105 Pain 71 (2003).

sales representatives, including those, it is believed, who wrote opioid prescriptions paid for by Plaintiff and other Workers' Compensation Payors.

674. Purdue also used its sales force to disseminate misleading statements about the ability of opioids to improve functionality.

VII. The damage caused by Defendants' fraudulent scheme.

675. Through their own direct promotional efforts, along with those of the third-party Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, the Manufacturing Defendants and their collaborators and accomplices accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain with opioids. As a result, doctors treating patients with common but persistent neck, back, joint and limb pain, including claimants of Plaintiff and other Workers' Compensation Payors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign.

676. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

677. Thus, Defendants put into motion events and circumstances where Plaintiff and other Workers' Compensation Carriers would be forced to pay huge and escalating costs to not only pay for the opioid medications, a huge expense in and of itself, but also for additional and prolonged medical care (including addiction

treatment and counseling), prolonged duration temporary disability payments, and in some instances, death benefits, which but for Defendant's deceptive acts, omissions and activities would not have been incurred.

A. Defendants' fraudulent and deceptive marketing of opioids directly caused harm to Plaintiff and the Workers' Compensation Payors.

678. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain was greatly successful. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide, rising to 257 million in 2009.¹²²

679. Opioid prescriptions increased even as the percentage of patients visiting doctors for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline of NSAID use.¹²³

680. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."¹²⁴ From 1980 to 2000,

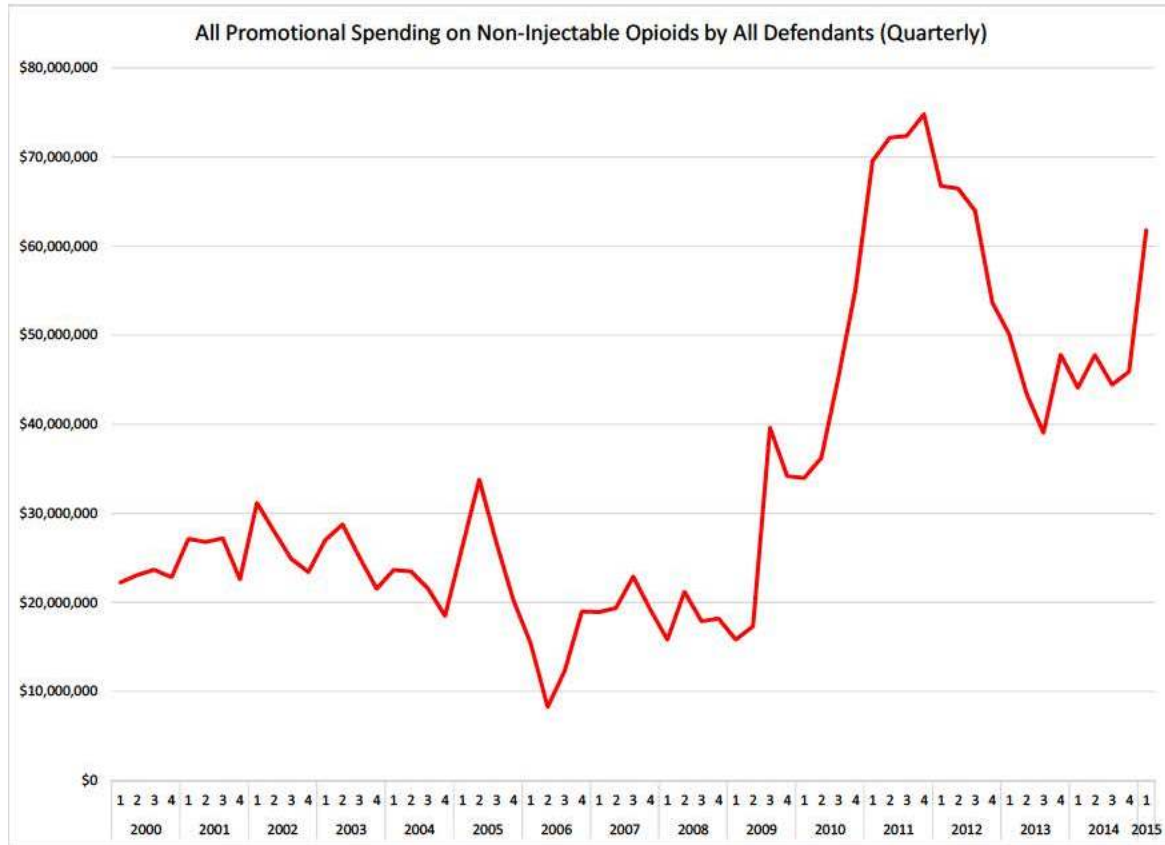
¹²² Office of National Drug Control Policy, *2011 Prescription Drug Abuse Prevention Plan*, Whitehouse.gov, (no longer available on whitehouse.gov), <https://obamawhitehouse.archives.gov/ondcp/prescription-drug-abuse1> (accessed November 18, 2019).

¹²³ Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).

¹²⁴ Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

opioid prescriptions for chronic pain visits doubled. This resulted not from an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications ***decreased***. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

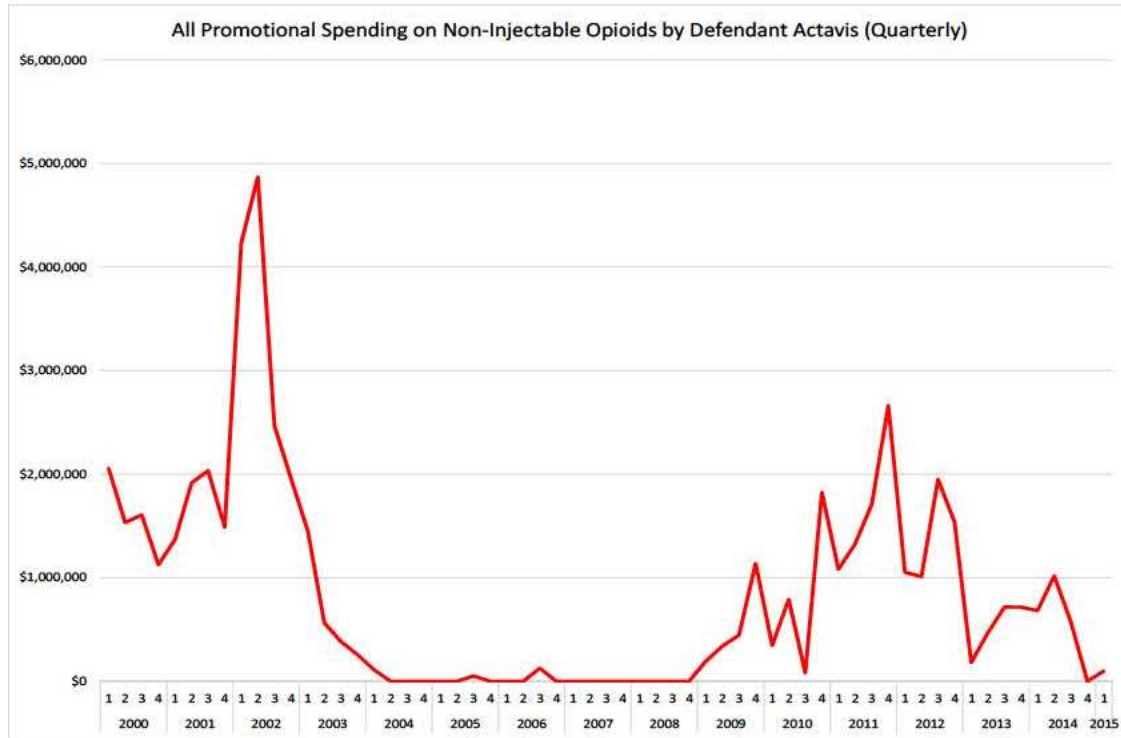
681. This increase corresponds with, and was caused by, Defendants’ massive marketing push. As reflected in the chart below, according to data obtained from a marketing research company, Defendants’ spending on marketing of opioids nationwide—including all of the drugs at issue here—stood at more than \$20 million per quarter and \$91 million annually in 2000. By 2011, that figure hit its peak of more than \$70 million per quarter and \$288 million annually, an increase of more than three-fold. By 2014, the figures dropped to roughly \$45 million per quarter and \$182 million annually, as Defendants confronted increasing concerns regarding opioid addiction, abuse, and diversion, and as Janssen, which accounted for most of the spending reduction, prepared to sell its U.S. rights to Nucynta and Nucynta ER. Even so, Defendants still spent double what they spent in 2000 on opioid marketing.



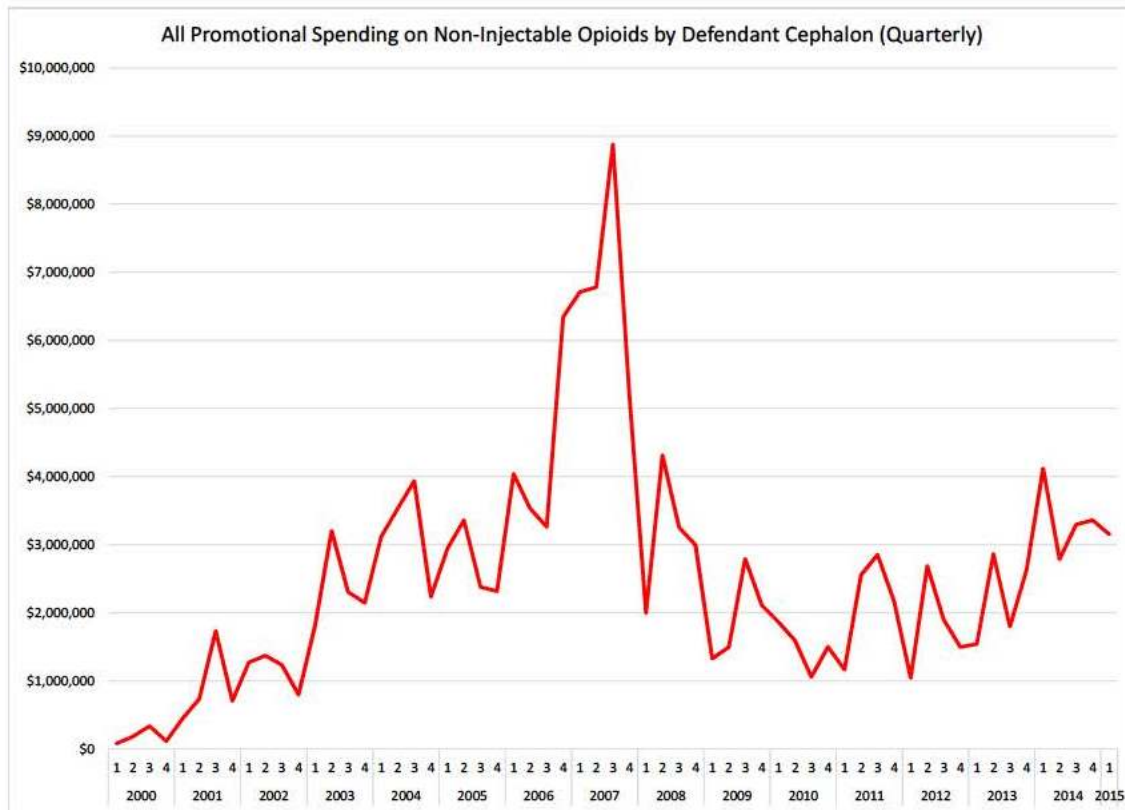
682. Defendants' opioid detailing visits to individual doctors made up the largest component of this spending, with total detailing expenditures more than doubling between 2000 and 2014 to \$168 million annually.

683. Each Defendant's promotional spending reflects its participation in this marketing blitz. Between 2000 and 2011:

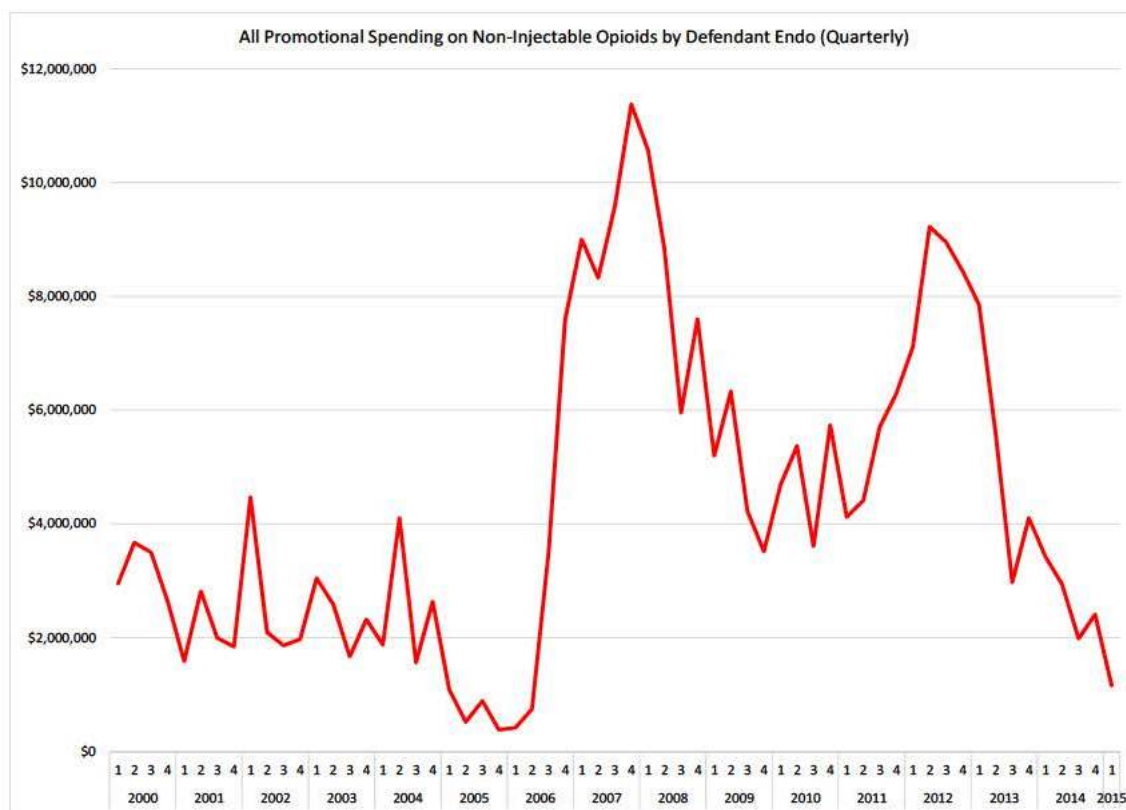
- Actavis's promotional spending, which was virtually nonexistent in the 2004-2008 period, began to sharply rise 2009. The third quarter of 2011 saw a peak of \$3 million at one point in 2011 and nearly \$7 million for the year, as shown below:



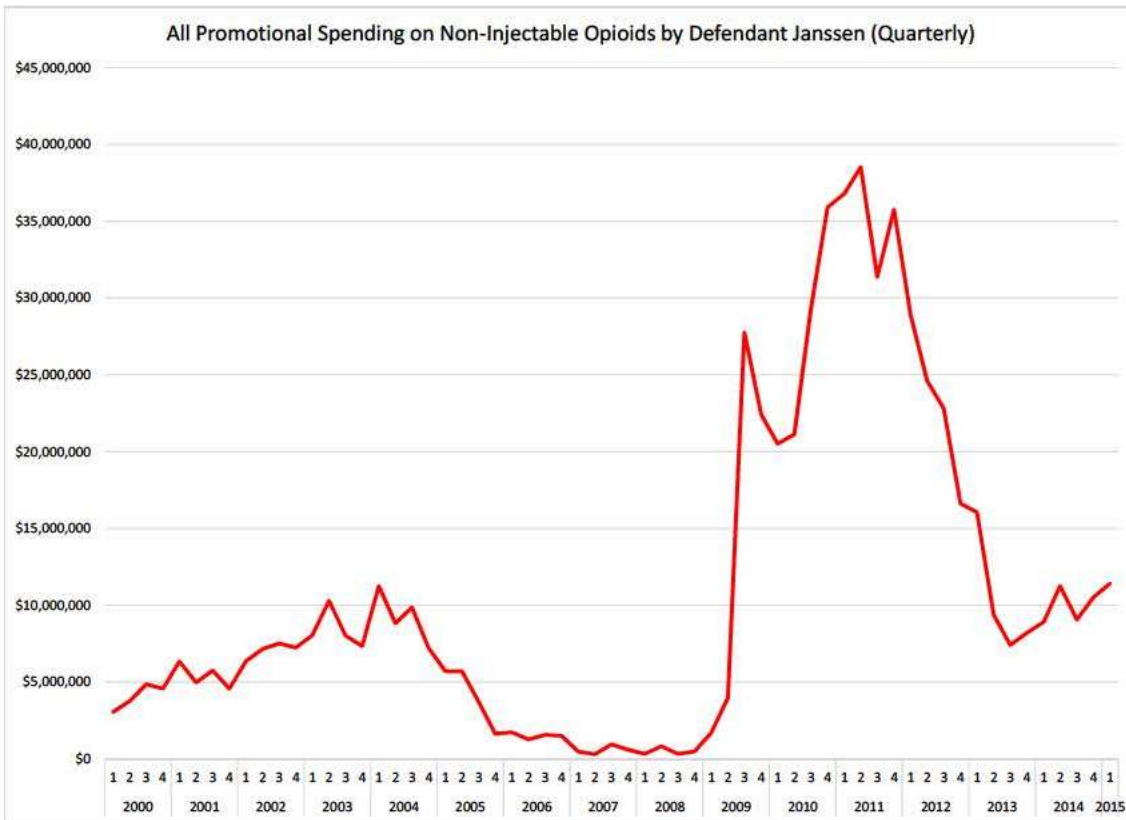
- Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$4 million in 2014 (and more than \$13 million for the year), including a peak, coinciding with the launch of Fentora, of nearly \$9 million half way through 2007 (and more than \$27 million for the year), as shown below:



- Endo's quarterly spending went from the \$2 million to \$4 million range from 2000 to 2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):



- Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011) as shown below:



- Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continued to rise, as shown below:



i. Plaintiff's increased spending on opioids

684. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend substantial sums on opioid prescriptions, most if not all of which expenditure was not necessary and due to Defendants' tortious acts, activities and omissions. Other Workers' Compensation Payors have incurred similar expenses for unnecessary (and harmful) opioid medication, which the National Council on Compensation Insurance has estimated to account for 25% of workers' compensation medical costs.

685. A study by CompPharma, LLC, reported that in 2015, workers' compensation carriers spent \$ 1.54 billion on opioids, which was 13% of the total

U.S. spend while the total medical spend by workers' compensation carriers was just 1.25%.¹²⁵

686. In addition, Plaintiff and other Workers' Compensation Payors incurred healthcare costs related to opioid use, addiction and abuse, greater disability benefits costs and other ascertainable damages and losses. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and the Workers' Compensation Payors.

687. Taken together, those costs are significant. For example, an analysis by the New York Times, demonstrates that without any opioid prescriptions, the average workers' compensation claim was in 2013, \$ 13,000.

More Workplace Costs

INSURANCE CLAIMS FOR TIME LOST
Workers' compensation costs include treatment expenses and lost wages. The stronger the opioid, the higher the expense.

Average claim cost without use of opioids:

 \$13,000

Cost with short-acting opioid like Percocet:

 \$39,000

Cost with long-acting opioid like OxyContin:

 \$117,000

¹²⁵ *Prescription Drug Management in Workers' Compensation*, CompPharma, LLC (2016), available at https://comppharma.com/wp-content/uploads/2016/10/2016CompPharmaPharmacySurvey.Final_.pdf (accessed on November 14, 2019).

With a short-term opioid prescription, that figure rose to \$ 39,000 and even higher with long-term opioid prescription at \$ 117,000: ¹²⁶

a. Defendants' misrepresentations were material.

688. Defendants' misrepresentations were material to, and influenced, the decisions of doctors to prescribe and Plaintiff and other Workers' Compensation Payors to pay claims for opioids for injured workers' non-cancer related chronic pain. That is, but for the Defendants' misleading doctors into accepting opioids as for treatment of non-oncological based chronic pain conditions, Plaintiff would not have been presented with, nor paid, thousands of bills/claims for opioids prescriptions as they did because the prescriptions would not have been written or administrative controls implemented. However, as the doctors, based upon the fraudulent marketing scheme of the Defendants as described throughout this Complaint, determined the use of opioids was medically indicated, necessary and proper for the injured workers they treated, Plaintiff and other Workers' Compensation Payors were obligated under law to pay for the prescriptions, the office visits associated with them, as well as any ensuing complications or prolonged disabilities relating to the claimants the injured workers' use of opioids.

689. Notably, Plaintiff's and other Workers' Compensation Payors' spending related to opioid utilization by injured workers rose along with Defendants'

¹²⁶ *The Soaring Cost of the Opioid Economy*, NYTIMES (June 2013), available at <https://archive.nytimes.com/www.nytimes.com/interactive/2013/06/23/sunday-review/the-soaring-cost-of-the-opioid-economy.html> (accessed on November 14, 2019).

spending to promote opioids. That spending was directly impacted by opioid use (and its consequences in abuse, addiction, and overdose).

B. Defendants’ fraudulent and deceptive marketing of opioids directly caused harm to Plaintiff and the Workers’ Compensation Payors.

690. Nationally, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse. “Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs.”¹²⁷ Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011—more than twice as many deaths as heroin and cocaine combined; drug poisonings now exceed motor vehicle accidents as a cause of death. More Americans have died from opioid overdoses than from participation in the Vietnam War.

691. Contrary to Defendants’ misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011. According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or “doctor-shoppers”) account for 20% of all prescription drug overdoses.

¹²⁷ Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

692. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

693. Emergency room visits tied to opioid use likewise have sharply increased.

i. Increased opioid use has increased the costs for Plaintiff and the Workers' Compensation Payors.

694. In addition to paying the cost of opioid prescriptions and opioid-related medical treatment, Plaintiff and the Workers' Compensation Payors provide other workers' compensation benefits, such as disability benefits for the periods when they cannot work while recovering from injuries, as well as treatment.

695. Plaintiff and the Workers' Compensation Payors have also expended significant funds on hospitalizations due to overdose, addiction treatment services, and overdose reversal medications.

696. These payments were the direct—and, indeed, intended—result of Defendants' scheme.

697. The payments for these prescriptions, treatment, and benefits were moreover not “medically necessary” in that opioids have not been scientifically proven effective for the treatment of chronic non-cancer pain.

698. One study by the Workers' Compensation Research Institute suggests that opioid prescriptions caused injured workers to incur longer durations of temporary disability leave.¹²⁸ In that study by the Workers' Compensation Research Institute, the researchers found that workers with longer-term opioid prescriptions had 251% longer duration of temporary disability benefits than workers with no opioid prescriptions, which implies that longer-term opioid use more than triples the duration of temporary disability benefits.

699. The Washington State Department of Labor and Industries has found that receiving more than a one-week supply of opioids after an injury doubles a worker's risk of disability one year later.¹²⁹

700. In yet another study, it was reported that when prescriptions for certain opioid pain medications were prescribed to claimants of workers' compensation, claims were almost four times as likely to have a total cost of **\$ 100,000** or more compared to claims without any prescriptions.¹³⁰

701. According to an annual workers' compensation report from Express Scripts, a pharmacy benefits manager, "the issue of opioid prescribing becomes even

¹²⁸ Bogdan Savych, et al , *The Impact of Opioid Prescriptions on Duration of Temporary Disability*, Workers' Compensation Research Institute (Mar. 6, 2018).

¹²⁹ Washington State Department of Labor and Industries, *Guidelines for Prescribing Opioids to Treat Pain in Injured Workers* (July 2013) <https://lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/FINALOpioidGuideline010713.pdf>.

¹³⁰ Jeffrey A. White, Xuguang Tao, Milan Talreja, Jack Tower & Edward Bernacki, *The effect of opioid use on workers' compensation claim costs in the State of Michigan*, J. of Occupational and Env'tl. Med., 54, 948-953 (2012).

more important in workers' compensation settings as prolonged opioid use has been shown to be associated with poorer outcomes, longer disability and higher medical costs for injured workers."¹³¹

702. By percentage of spend, the National Council on Compensation Insurance has estimated that 25% of workers' compensation medical costs result from opioid usage.

ii. Defendants' fraudulent marketing led to record profits.

703. All the while the use of opioids has taken an enormous toll on Plaintiff, the Workers' Compensation Payors, and their claimants, Defendants have gained blockbuster profits. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers¹³²—roughly one prescription per American adult. Opioids generated \$8 billion in revenue for drug companies just in 2010.

704. Financial information—where available—indicates that Defendants each experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above.

705. Purdue's OxyContin sales alone increased from \$45 million in 1996 to \$3.1 billion in 2010.

¹³¹ 2012 Workers' Compensation Drug Trend Report, Express Scripts (April 2013).

¹³² Press Release, Center for Disease Control, Opioid painkiller prescribing varies widely among states: Where you live makes a difference (July 1, 2014), <https://www.cdc.gov/media/releases/2014/p0701-opioid-painkiller.html> (accessed November 18, 2019).

iii. Defendants fraudulently concealed their misrepresentations.

706. At all times relevant to this Complaint, Defendants took steps to avoid detection of, and fraudulently conceal, their deceptive marketing and conspiratorial behavior.

707. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

708. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. Defendants exerted their considerable influence on these promotional and “educational” materials.

709. In addition to hiding their own role in generating the deceptive content, the Manufacturing Defendants manipulated their promotional materials and the scientific literature to make it appear as if they were accurate, truthful, and supported by substantial scientific evidence. The Manufacturing Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions they did not actually support. The true lack of support for these Defendants’ deceptive messages was not apparent to the medical professionals who

relied upon them in making treatment decisions, nor could they have been detected by Plaintiff and the Workers' Compensation Payors.

710. Thus, while the opioid epidemic was evident, the Manufacturing Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and third-party payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now assert. Plaintiff was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

VIII. The Distributor Defendants flooded the market with suspiciously large amounts of opioids.

711. The Distributor Defendants purchased opioid medications from drug manufacturers, such as the named Defendants herein, on a wholesale basis and sold them to pharmacies as part of the Opioid Supply Chain Enterprise.

712. The Distributor Defendants played an integral role in the chain of opioids being distributed.

713. Pursuant to the federal Controlled Substances Act, distributors and wholesalers such as Distributor Defendants are required to establish and maintain secured inventories and records on all transactions of controlled substance drugs such as opioid pain medications.

714. The Manufacturing and Distributor Defendants knew that the controlled substances they manufactured and distributed were the kinds that were susceptible to diversion for distribution through illegal or illegitimate distribution

channels to a lucrative black market for the drugs related to the opiate crisis, which created an epidemic of opiate medication addicts, which further increased the costs to Plaintiff and the other Workers' Compensation Payors for addiction treatment and disability and death benefits.

715. The Manufacturing and Distributor Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers during this time period.

716. As entities involved in the manufacture and distribution of opioid medications, the Manufacturing and Distributor Defendants were engaged in abnormally and/or inherently dangerous activity they had a duty to prevent and/or avoid.

717. The Manufacturing and Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA.

718. The Manufacturing and Distributor Defendants knew or should have known that they were supplying vast amounts of dangerous drugs to the claimants of Plaintiff and the Workers' Compensation Payors that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

719. The Manufacturing and Distributor Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs, which resulted in a huge diversion of opioid medications into illicit distribution channels. The diversion caused further injury to injured workers who had become dependent or

addicted on opiates that they were initially prescribed by doctors treating their work injuries, but limited or restricted the amounts they would prescribe the worker.

720. The Manufacturing and Distributor Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the manufacture and flow of these drugs to claimants of Plaintiff and the Workers' Compensation Payors.

721. The Manufacturing and Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

722. The Manufacturing and Distributor Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

723. In 2008, McKesson paid a \$13.25 million fine to settle similar claims regarding suspicious orders from internet pharmacies.¹³³

724. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

725. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."¹³⁴

¹³³ <http://www.wvgazettemail.com/news-health/20161218/suspicious-drug-order-rules-never-enforced-by-state> (accessed November 18, 2019).

¹³⁴ <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders> (accessed November 18, 2019).

726. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record \$150 million fine and suspend the sale of controlled substances from distribution centers in several states.¹³⁵

727. In 2008, Defendant Cardinal paid a \$34 million penalty to resolve allegations that it failed to report suspicious opioid orders.¹³⁶

728. Despite this past penalty, in 2017, it was announced that Defendant Cardinal agreed to a \$44 million fine to “resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York.”¹³⁷

729. Defendant AmeriSource faced a criminal inquiry “into its oversight of painkiller sales” in 2012.¹³⁸ They have paid out fines for similar claims to the state of West Virginia.

730. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids to the claimants of Plaintiff and the Workers’ Compensation Payors.

¹³⁵ *Id.*

¹³⁶ <https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0> (access November 18, 2019).

¹³⁷ https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.7049c4431465 (accessed on November 18, 2019).

¹³⁸ <http://www.nytimes.com/2013/06/12/business/walgreen-to-pay-80-million-settlement-over-painkiller-sales.html> (accessed on November 18, 2019).

731. The Distributor Defendants are also members of the Healthcare Distribution Management Association (“HDMA”). The HDMA created “Industry Compliance Guidelines” which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that “[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

732. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into the market.

733. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

734. The sheer volume of the increase in opioid pain medications being distributed to retailers, should have put the Defendants on notice to investigate and report such orders.

735. The Manufacturing Defendants manufactured and delivered an excessive and unreasonable amount of opioid pain medications to retailers.

736. Upon information and belief, the Manufacturing Defendants did not refuse to manufacture, ship, or supply any opioid medications to any from 2007 to the present.

737. The Defendants knew or should have known that they were manufacturing and distributing levels of opioid medications that far exceeded the legitimate needs of the public and legitimate patients.

738. The Defendants also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications.

739. The Defendants made substantial profits from the opioids sold.

740. The Manufacturing and Distributor Defendants violated the Controlled Substances Act's provisions and regulations for manufacturers and distributors, including the aforementioned, by failing to properly report suspicious orders.

741. By the actions and inactions described above, the Manufacturing and Distributor Defendants showed a reckless disregard for the safety of the claimants of Plaintiff and Workers' Compensation Payors.

742. By the actions and inactions described above, the Manufacturing and Distributor Defendants caused great harm to the claimants of Plaintiff and Workers' Compensation Payors through additional costs for addiction treatment and disability and death benefits. While Plaintiff and the other Workers' Compensation Payors did not pay for the opioid pain medications that their claimants obtained through the black market, the availability of such drugs has resulted in Plaintiff and the other Workers' Compensation Payors sustaining other costs because of their responsibility to pay for medical and addiction treatment and temporary and permanent disability benefits, all of which are increased due to the availability of opioid pain medications through other channels.

743. On December 27, 2007, the U.S. Department of Justice, Drug Enforcement Administration, sent a letter to Cardinal stating, “This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b).”

744. The DEA has provided briefings to each of the Defendant Distributors and conducted a variety of conferences regarding their duties under federal law.

745. The DEA sent a letter to each of the Defendant Distributors on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

746. The DEA sent a second letter to each of the Defendant Distributors on December 27, 2007. This letter reminded the Defendant Distributors of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (*e.g.*, “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually

characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.

747. As a result of the decade-long refusal by the Defendant Distributors to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The public record reveals many of these actions:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (Orlando Facility) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (Auburn Facility) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (Lakeland Facility) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (Swedesboro

Facility) for failure to maintain effective controls against diversion of hydrocodone;

- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (Stafford Facility) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (2008 MOA) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility, and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (McDonough Facility), Valencia, California (Valencia Facility) and Denver, Colorado (Denver Facility);
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (Lakeland Facility) for failure to maintain effective controls against diversion of oxycodone;
- i. On June 11, 2013, Walgreens paid \$80 million in civil penalties for dispensing violations under the CSA regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies in Florida;
- j. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

- k. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA

748. In 2007, Belco agreed to pay a \$800,000 fine for its failure to report to the DEA “suspicious orders” equaling 2,288 shipments of hydrocodone between January 2005 and April 2007.

749. On December 19, 2016, Preet Bharara, Esq., then United States Attorney for the Southern District of New York, and James Hunt, Special Agent in Charge for the DEA, announced the filing and settlement of a civil lawsuit involving Controlled Substances Act (“CSA”) claims brought by the United States against Kinray.¹³⁹

750. On December 22, 2016, Kinray agreed to pay \$10 million to the United States, and admitted and accepted responsibility for failing to inform the DEA, as required by CSA regulations, of Kinray’s receipt of suspicious orders for certain controlled substances during the time period between January 1, 2011 and May 14, 2012.¹⁴⁰

751. As alleged, during the period from January 1, 2011 to May 14, 2012, the DEA investigated pharmacies in New York City and elsewhere that had placed

¹³⁹ *Id.*

¹⁴⁰ *Id.*

orders for shipments of oxycodone or hydrocodone (both Schedule II controlled substances) from Kinray that were of unusual size and/or unusual frequency.¹⁴¹ For example, the DEA's internal tracking system revealed that during the relevant period, Kinray had shipped oxycodone or hydrocodone to more than 20 New York-area pharmacy locations that placed orders for a quantity of controlled substances many times greater than Kinray's average sales of controlled substances to all of its customers.¹⁴² Such orders should have triggered "red flags" in Kinray's ordering system, and Kinray should have reported the suspicious orders to the DEA. But for most of this time period, Kinray did not report a single suspicious order to the DEA.¹⁴³

752. On July 9, 2015, Preet Bharara, the former United States Attorney for the Southern District of New York, James J. Hunt, the Special Agent-in-Charge of the New York Field Division of the U.S. DEA, and William J. Bratton, the former Commissioner of the New York City Police Department ("NYPD"), announced that the United States filed and settled a civil lawsuit against Rochester Drug.¹⁴⁴

753. Under the settlement, Rochester Drug admitted and accepted responsibility for numerous violations of the CSA, and agreed to pay \$360,000 in

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Press Release, U.S. Dep't of Justice, Manhattan U.S. Attorney Recovers \$360,000 In Civil Penalties From A Rochester Pharmaceutical Company That Violated The Controlled Substances Act (Dec. 2, 2019), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-recovers-360000-civil-penalties-rochester-pharmaceutical-company>.

penalties and to re-submit to DEA corrected record-keeping reports required by the CSA.¹⁴⁵

754. The Complaint against Rochester Drug alleged that, following an audit of various pharmacies in the New York City area, the DEA discovered that the pharmacies had reported thousands of purchase orders from Rochester Drug that Rochester Drug did not correspondingly report to the DEA through ARCOS.¹⁴⁶ In response, in 2013, the DEA's New York Field Division Tactical Diversion Squad conducted an on-site investigation and audit at Rochester Drug's headquarters in Rochester, New York. The DEA's audit confirmed that Rochester Drug's ARCOS reporting system was underreporting many thousands of drug sales to pharmacies throughout the northeast region.¹⁴⁷

755. Rochester Drug responded that it expected to be able to resolve this issue through the pending acquisition of a new computer ordering system.¹⁴⁸ But in 2014, DEA re-assessed Rochester Drug's compliance, and discovered that Rochester Drug had not implemented the new order system.¹⁴⁹ As a result, Rochester Drug's failure to electronically report thousands of shipments of CSA-controlled substances, including Oxycodone and its variants, continued.¹⁵⁰ During this time,

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

the DEA also determined that Rochester Drug had failed to report the theft or significant loss of controlled substances in ARCOS, as required by the CSA and its implementing regulations.¹⁵¹

756. In the settlement agreement, Rochester Drug admitted that between July 2013 and July 2014, it failed to report any electronic distribution transactions in its DEA ARCOS reports, and admitted that between July 2012 and July 2014, it failed to provide the required theft or significant loss reporting in ARCOS to the DEA.¹⁵² Under the Consent Order, Rochester Drug paid \$360,000 in civil penalties to the United States and reconstruct complete and correct historical ARCOS data for the last five years for submission to the DEA.¹⁵³

757. Rather than abide by these public safety statutes, the Defendant Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

“imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.¹⁵⁴

IX. Defendants entered into and engaged in a civil conspiracy.

758. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their conspiratorial enterprise.

759. Defendants reached an agreement between themselves to establish, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

760. This network is interconnected and interrelated and relied upon Defendants’ collective use of, and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and

¹⁵⁴ See Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.d84d374ef062; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b44410552cde.

Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

761. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

CLASS ACTION ALLEGATIONS

762. Plaintiff brings this action on behalf of itself and pursuant to Rules 23(b)(2), (b)(3) and (c)(4) of the Federal Rules of Civil Procedure on behalf of a class of Workers' Compensation Payors (the "Class" or "Workers' Compensation Payors") defined as follows:

During the fullest period allowed by law, all workers' compensation insurers and self-insured employers in the United States (including territories and possessions) which pay for and provide injured workers worker's compensation benefits, including medical treatment and prescription drug benefits as well as disability and death benefits, and has paid or is obligated to pay injured workers' compensation benefits related to injured workers use of opioid medications in connection with the treatment of the injured workers' injuries and not for acute pain, surgical recovery, cancer treatment, or end-of-life palliative care.

Excluded from the Class, however, are Workers' Compensation Payors that are agencies or part of any federal, state or U.S. territorial governments.

763. Plaintiff reserves the right to amend the Class definition if discovery and further investigation reveal that the Class should be expanded or otherwise modified.

764. **Numerosity/Impracticability of Joinder**: The members of the Class are so numerous that joinder of all members would be impracticable.

765. **Commonality and Predominance:** There are common questions of law and fact that predominate over any questions affecting only individual Class members. For example, whether the Defendants herein violated such laws identified below in the deceptive marketing, distribution, and dispensing of opioid medications. Moreover, common legal and factual questions, include, but are not limited to the following aspects of Defendants' unlawful practices:

- (a) Each Defendants' role in creating the opioid epidemic;
- (b) Whether the Defendants herein misrepresented the safety and efficacy of opioid pain medications;
- (c) Whether Defendants deliberately misrepresented the safety of opioid pain medications so that Workers' Compensation Payors would pay for the drugs;
- (d) Whether the payments made by Workers' Compensation Payors for opioid prescriptions, treatment and disability benefits were the foreseeable and natural consequence of the Opioid Marketing Enterprise;
- (e) Whether Defendants' Opioid Marketing Enterprise could have been successful without Workers' Compensation Payors and other Third-Party Payors coverage of opioid pain medications;
- (f) Whether the Defendants caused or are responsible for the diversion of opioid medication from legitimate distribution and medical channels into illicit distribution channels, adding to the opioid epidemic and the injury and harm sustained by the Class Members' claimants;

(g) Whether the actions of the Defendants caused Workers' Compensation Payors to suffer economic damages and losses;

(h) Whether Class members are entitled to payment of actual, incidental, consequential, exemplary and/or statutory damages plus interest thereon, and if so, what is the nature of such relief;

(i) Whether the Court should under the circumstances certify a settlement negation class of Workers' Compensation Payors; and

(j) Whether Class members are entitled to disgorgement, etc.

766. **Typicality**: Plaintiff's claims are typical of the claims of the Workers' Compensation Payors. Plaintiff and Class members have been injured by the same wrongful practices of Defendants. Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of the Class members and are based on the same legal theories. Plaintiff also suffered the same categories of damages, *i.e.*, financial loss resulting from the coverage of opioid prescriptions, treatment and disability benefits.

767. **Adequacy**: Plaintiff is a representative who will fully and adequately assert and protect the interests of the Class and has retained class counsel who are experienced and qualified in prosecuting class actions. Neither Plaintiff nor their attorneys have any interests contrary to or conflicting with the Class.

768. **Superiority**: A class action is superior to all other available methods for the fair and efficient adjudication of this lawsuit, because individual litigation of the claims of all Class members is economically unfeasible and procedurally

impracticable. While the aggregate damages sustained by the Class are likely in the hundreds of millions of dollars, if not billions, the individual damages incurred by each Class member may be relatively too small to warrant the expense of individual suits. The likelihood of individual Class members prosecuting their own separate claims is remote. The court system would also be unduly burdened by individual litigation of such cases. Further, individual members of the Class do not have a significant interest in individually controlling the prosecution of separate actions, and individualized litigation would also result in varying, inconsistent, or contradictory judgments and would magnify the delay and expense to all of the parties and the court system because of multiple trials of the same factual and legal issues. Plaintiff is not aware of any difficulty to be encountered in the management of this action that would preclude its maintenance as a class action. In addition, Defendants have acted or refused to act on grounds generally applicable to the Class and, as such, final injunctive relief or corresponding declaratory relief with regard to the members of the Class as a whole is appropriate.

769. Plaintiff does not anticipate any difficulty in the management of this litigation.

CAUSES OF ACTION

COUNT I

VIOLATION OF RICO, 18 U.S.C. § 1961, ET SEQ. (Against the Manufacturing and Front Group Defendants)

770. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

771. At all relevant times, the Manufacturing Defendants and Front Group Defendants were and are “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

772. The Manufacturing Defendants and Front Group Defendants each conducted the affairs of an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), referred to herein as the “**Opioid Marketing Enterprise**”, which consisted of the Manufacturing Defendants and Front Group Defendants, together with the Bankrupt Purdue Companies, and KOLs who are not named as defendants. The activities of this enterprise affected interstate commerce.

773. The Opioid Marketing Enterprise’s purpose and mission was to engage in, conduct, facilitate or finance activities to generate, increase and maintain sales, revenues, income and profits derived from the promotion, marketing and/or sale of prescription both brand name opioid drugs and generic equivalents through the knowing and intentional dissemination of false and misleading information about the attributes, safety and efficacy of opioid use in general and in particular their longer-term use in treating chronic pain conditions.

774. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each member of the Opioid Marketing Enterprise; (b) was separate and distinct from the pattern of racketeering in which the Manufacturing and Front Group Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Manufacturing and Front Group Defendants; (d) was

characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the Manufacturing and Front Group Defendants and between them and the Bankrupt Purdue Companies and each of the KOLs; (e) had a *de facto* hierarchical structure whereby Front Groups and KOLs, were subordinate to the Manufacturing Defendants who exercised control over the Front Group and KOLs' activities in furtherance of the enterprise's purpose and goals; (f) had sufficient longevity for the Opioid Marketing Enterprise to pursue its purpose; and (g) functioned as a continuing unit.

775. In particular, each of the Manufacturing and Front Group Defendants, Bankrupt Purdue Companies and KOLs, that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through (a) joint participation in lobbying groups; (b) medical and industry organizations; (c) contractual relationships; (d) grants; and (d) continuing coordination of activities. These systematic links and personal relationships allowed members of the Opioid Marketing Enterprise to act with a common purpose and to conduct and participate in the conduct of the Opioid Marketing Enterprise. Moreover, each of the Manufacturing and Front Group Defendants coordinated their efforts through the same KOLs and respective Front Groups' personnel, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work together with the Manufacturing and Front Group Defendants (as well as with the Bankrupt Purdue Companies) to advance the common purpose and goals of the Opioid Marketing Enterprise. Further, each

component of the Opioid Marketing Enterprise benefited from the existence of the other parts.

776. Each of the Manufacturing and Front Group Defendants, as member of the Opioid Marketing Enterprise, conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a role and performing the acts and activities described above in furtherance of accomplishing the Enterprise's common purposes, including, among other things: (a) the Manufacturing Defendants' development and implementation of extensive campaigns of false and misleading advertising, promotional mailings and in person detailing of the opioid medications to prescribers which promoted or defended the wider use of opioid medications than what was stated in their FDA labels' indications or supported by medical science; and (b) under the guise of being independent and trustworthy sources of fair, balanced and scientifically/medically valid current information, the Front Group Defendants' respective publishing of recommendations, articles, statements, guidelines, standards of care and websites and/or their sponsoring of CME's and lectures which promoted or defended the wider use of opioid medications than what was stated in their FDA labels' indications or supported by medical science; and (c) the KOLs serving as lecturers, spokespersons or authors in media which promoted or defended the wider use of opioid medications than what was stated in their FDA labels' indications or supported by medical science. In so doing, each of the Manufacturing and Front Group Defendants conducted and participated in the

conduct of the Opioid Marketing Enterprise by engaging in a pattern of racketeering activities, mail and wire fraud, in violation of 18 U.S.C. § 1962(c).

777. The Manufacturing and Front Group Defendants each worked together to coordinate the Opioid Marketing Enterprise's goals and conceal their actual roles, as well as the Opioid Marketing Enterprise's existence, from the public by, among other things: (i) funding, editing, and distributing publications that supported and advanced their false messages; (ii) funding KOLs to promote their false messages; (iii) funding, editing, and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (that is, sales detailing).

778. Each of the Front Groups helped disguise the role of the Manufacturing Defendants (and the Bankrupt Purdue Companies) by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials—a body of biased and unsupported scientific “literature,” and “treatment guidelines” that promoted the Defendants’ false messages.

779. Each of the KOLs was a physician chosen and paid by one or more of the Manufacturing Defendants (and the Bankrupt Purdue Companies) to influence prescribers’ habits by promoting the Defendants’ false message through, among other things, writing favorable journal articles and delivering supportive speeches and CMEs as if they were independent medical professionals, thereby further

obscuring the Manufacturing Defendants' role in the Opioid Marketing Enterprise and the Opioid Marketing Enterprise's existence.

780. The Manufacturing and Front Group Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5) that employed the use of mail and interstate wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids.

781. The Manufacturing and Front Group Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud.

782. For the fraudulent scheme to work, each of the Manufacturing and Front Group Defendants had to agree to implement similar tactics. Also integral to the success of the Opioid Marketing Enterprise was that third-party payors such as Plaintiff and the Class of Workers' Compensation Payors would pay for the opioid medications, which but for the illegal conduct and deceit members of the enterprises' members and accomplices they would not have.

783. As summarized herein, Manufacturing and Front Group Defendants repeatedly and often used the mail and interstate wires to send or receive thousands of communications, emails, publications, representations, statements, electronic transmissions, and payments to carry out the Opioid Marketing

Enterprise's fraudulent scheme. The Manufacturing and Front Group Defendants' predicate acts of racketeering activity, 18 U.S.C. § 1961(1), therefore consisted of:

(a) Mail Fraud: Defendants violated 18 U.S.C. § 1341 and § 1346 by frequently sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to market, promote, expand the use and sell prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

(b) Wire Fraud: Defendants violated 18 U.S.C. § 1343 and § 1346 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wires, including telephone calls, fax transmission, and the use of the internet (emails and websites) for the purpose of executing the unlawful scheme to market, promote, expand the use and sell prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

784. Because the Manufacturing and Front Group Defendants disguised their participation in the Opioid Marketing Enterprise, and worked to keep even the Opioid Marketing Enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise

depended upon secrecy. Nonetheless, Plaintiff has described occasions on which the Marketing Manufacturing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to consumers, prescribers, regulators, and how those acts were in furtherance of the scheme.

785. The Manufacturing and Front Group Defendants each committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Marketing Manufacturing Defendants committed, conspired to commit, and/or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity and/or constituted continuous racketeering activity, and therefore constituted a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise. Defendants participated in the scheme to defraud by using mail and interstate wires (including telephones and the Internet) in interstate or foreign commerce.

786. Each of the Manufacturing and Front Group Defendants not only violated the above laws but also aided and abetted others in the violations of the above laws, thereby rendering the Defendants indictable as principals.

787. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the

future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

788. The Manufacturing and Front Group Defendants' multiple and predicate acts and pattern of racketeering activity were a proximate cause of the opioid epidemic that has injured Plaintiff and the Workers' Compensation Payors in the form of substantial losses of money and property that logically, directly, and foreseeably arose from the opioid epidemic brought on by the Manufacturing and Front Group Defendants' acts.

789. The Manufacturing and Front Group Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Plaintiff and Workers' Compensation Payors Class members injury to their business and property.

790. By virtue of these violations of 18 U.S.C. § 1962(c), the Manufacturing and Front Group Defendants are liable to Plaintiff and Class members for three times the damages they have sustained, plus costs.

COUNT II

VIOLATION OF RICO, 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c) (Against Manufacturing and Front Group Defendants)

791. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

792. Section 1962(d) of RICO provides that it “shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section.”

793. The Manufacturing and Front Group Defendants violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c) with the companies, organizations physicians and other persons who participated in the Opioid Marketing Enterprise. The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Opioid Marketing Enterprise, described previously, through a pattern of racketeering activity.

794. The Manufacturing and Front Group Defendants and their respective co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud or deceive members of the medical profession and the public regarding the safety, efficacy and utility of opioid drugs in treating chronic pain.

795. Manufacturing and Front Group Defendants and their co-conspirators sought to and have engaged in the commission of and continues to commit overt acts, including the following unlawful racketeering predicate acts:

- (a) multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;
- (b) multiple instances of wire fraud violations of 18 U.S.C. §§ 1343 and 1346; and,

(c) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

796. The nature of the above-described co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were also aware that their ongoing fraudulent and criminal acts have been and are part of an overall pattern of racketeering activity.

797. As a direct and proximate result of Manufacturing and Front Group Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and members of the Class have been and are continuing to be injured in their business or property as set forth more fully above. By reason of the unlawful acts engaged in by Manufacturing and Front Group Defendants and their co-conspirators, Plaintiff and members of the Class have suffered ascertainable loss and damages.

798. Injuries suffered by Plaintiff and member of the Class were directly and proximately caused by Manufacturing and Front Group Defendants' racketeering activity as described above.

799. By virtue of these violations of 18 U.S.C. § 1962(d), the Manufacturing and Front Group Defendants are liable to Plaintiff and Class members for three times the damages Plaintiff and members of the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

COUNT III

**VIOLATION OF RICO, 18 U.S.C. § 1961, *ET SEQ.*
(Against Manufacturing and Distributor Defendants)**

800. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

801. At all relevant times, the Manufacturing and Distributor Defendants were and are “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

802. The Manufacturing and Distributor Defendants each conducted the affairs of an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), referred to herein as the “**Opioid Supply Chain Enterprise**”.

803. The Opioid Supply Chain Enterprise’s purpose and mission was to increase the quota for and profiting from the increased volume of opioid sales in the United States, including but not limited to creating or fostering a market for non-medical use of opioids of epidemic proportions. The Opioid Supply Chain Enterprise was an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4) consisting of which consisted of the Manufacturing and Distributor Defendants, together with the Bankrupt Purdue Companies which are not named as defendants. The activities of the Opioid Supply Chain Enterprise affected interstate commerce.

804. While participating in or conducting the affairs of the Opioid Supply Chain Enterprise, the Manufacturing and Distributor Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders

that the Defendants were supplying or filling on a daily basis—leading to the diversion of hundreds of millions of doses of name-brand and generic prescription opioids into the illicit market.

805. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each member of the Opioid Supply Chain Enterprise; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Supply Chain Enterprise, *i.e.*, the Manufacturing and Distributor Defendants; (e) had sufficient longevity for the Opioid Supply Chain Enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the Enterprise through a pattern of racketeering activity and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and the resulting sales.

806. Many of the Manufacturing and Distributor Defendants are members, participants, and/or sponsors of the Healthcare Distribution Alliance (“HDA”), an industry group that published Industry Compliance Guidelines for reporting suspicious orders and preventing diversion, and have been since at least 2006. The Manufacturing and Distributor Defendants utilized the HDA to form the systematic links and interpersonal relationships of the Opioid Supply Chain Enterprise and to

assist the Manufacturing and Distributor Defendants in engaging in the pattern of racketeering activity that gives rise to this Count.

807. The Manufacturing and Distributor Defendants conducted and participated in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5) in connection with each of the Manufacturing and Distributor Defendants participated by playing a role and performing the acts and activities described herein in order to accomplish and achieve the Enterprise's common purposes

808. The pattern of racketeering activity of the Opioid Supply Chain Enterprise included the use of mail and interstate wire facilities, in furtherance of a scheme to defraud Federal and state regulators, the American public, and the Nation in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

809. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Manufacturing and Distributor Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

810. The pattern of racketeering activity of the Opioid Supply Chain Enterprise also included the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person knowingly or intentionally to furnish false or fraudulent

information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of 21 U.S.C. § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1). The Manufacturing and Distributor Defendants violated 21 U.S.C. § 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material information from, reports, records, and other documents required to be made, kept, and filed under the relevant subchapter of Title 21 of the United States Code.

811. The pattern of racketeering activity of the Opioid Supply Chain Enterprise also included violations of the Travel Act, 18 U.S.C. § 1952. Manufacturing and Distributor Defendants violated 18 U.S.C. § 1952 in that they used interstate facilities, the United States mail, telephones, internet and other facilities in interstate commerce with the intent to carry on, or facilitate the carrying on of, an “unlawful activity” within the meaning of 18 U.S.C. § 1952(b), namely, a business enterprise involving controlled substances, and thereafter carried on such unlawful activity, in violation of the controlled substances laws of the United States as well as those of several states, including the Commonwealths of Massachusetts and Pennsylvania and the States of California, New Jersey, New York, and Illinois, all of which Plaintiff and members of the Workers’ Compensation Payors Class provided Workers’ Compensation benefits in. By turning a blind eye to diversion, Defendants aided and abetted the unlawful distribution and dispensing

of prescription opioids, which in turn injured or exacerbated the injuries of injured workers it was providing medical and disability benefits to.

812. In sum, the Manufacturing and Distributor Defendants' predicate acts of racketeering activity (18 U.S.C. § 1961(1)) consisted of:

(a) Mail Fraud: The Manufacturing and Distributor Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

(b) Wire Fraud: The Manufacturing and Distributor Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wire for the purpose of executing the unlawful scheme to market, promote and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

(c) Controlled Substance Violations: The Manufacturing and Distributor Defendants who are Distributor Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA; and

(d) Travel Act Violations: The Manufacturing and Distributor Defendants violated 18 U.S.C. § 1952 by using the mail and facilities in interstate commerce

with the intent to carry on, or facilitate the carrying on of, an unlawful activity, namely, a business enterprise involving controlled substances.

813. The Manufacturing and Distributor Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud, mail fraud and wire fraud.

814. Indeed, for the Manufacturing and Distributor Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics.

815. Each of the Manufacturing and Distributor Defendants not only violated the above laws but aided and abetted others in the violations of the above laws, thereby rendering Defendants indictable as principals.

816. Many of the precise dates of the Manufacturing and Distributor Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Manufacturing and Distributor Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

817. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

818. It was foreseeable to the Manufacturing and Distributor Defendants that the Plaintiff and the Workers' Compensation Payors would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the FCSA and Code of Federal Regulations allowed the

widespread diversion of name-brand and generic prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the FCSA intended to prevent, which resulted in additional costs to Plaintiff and the Workers' Compensation Payors in the form of coverage of addiction treatment and disability benefits.

819. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

820. The Manufacturing and Distributor Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Plaintiff and the Workers' Compensation Payors' injuries in their business and property. The Manufacturing and Distributor Defendants' pattern of racketeering activity, including their refusal to identify, report, and halt suspicious orders of controlled substances, logically, substantially, and foreseeably caused an opioid epidemic. The Plaintiff and the Workers' Compensation Payors were injured and continues to be injured by the Manufacturing and Distributor Defendants' pattern of racketeering activity and the opioid epidemic that it created.

821. The Manufacturing and Distributor Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA and knew that opioids were highly addictive and subject to abuse. Nevertheless, in order to increase sales of their opioid products, the Manufacturing and Distributor Defendants engaged in a scheme of deception by refusing to identify or report

suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the market of non-medical use. They did so by utilizing the mail and interstate wires as part of their fraud.

822. The Manufacturing and Distributor Defendants' predicate acts and pattern of racketeering activity were a proximate cause of the opioid epidemic that has injured Plaintiff and the Workers' Compensation Payors in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid epidemic brought on by the Defendants' acts.

823. The Manufacturing and Front Group Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Plaintiff and Workers' Compensation Payors Class members injury to their business and property.

824. By virtue of these violations of 18 U.S.C. § 1962(c), the Manufacturing and Distributor Defendants are liable to Plaintiff and Class members for three times the damages they have sustained, plus the cost.

COUNT IV

VIOLATION OF RICO, 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)

(Against Manufacturing and Distributor Defendants)

825. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

826. Section 1962(d) of RICO provides that it “shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section.”

827. The Manufacturing and Distributor Defendants violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c) with the companies, organizations physicians and other persons who participated in the Opioid Marketing Enterprise. The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Opioid Marketing Enterprise, described previously, through a pattern of racketeering activity.

828. The Manufacturing and Distributor Defendants and their respective co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud or deceive members of the medical profession and the public regarding the safety, efficacy and utility of opioid drugs in treating chronic pain.

829. The Manufacturing and Distributor Defendants and their co-conspirators sought to and have engaged in the commission of and continues to commit overt acts, including the following unlawful racketeering predicate acts:

- (a) multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;
- (b) multiple instances of wire fraud violations of 18 U.S.C. §§ 1343 and 1346; and,

(c) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

830. The nature of the above-described co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were also aware that their ongoing fraudulent and criminal acts have been and are part of an overall pattern of racketeering activity.

831. As a direct and proximate result of Manufacturing and Distributor Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and members of the Class have been and are continuing to be injured in their business or property as set forth more fully above. By reason of the unlawful acts engaged in by Manufacturing and Distributor Defendants and their co-conspirators, Plaintiff and members of the Class have suffered ascertainable loss and damages.

832. Injuries suffered by Plaintiff and member of the Class were directly and proximately caused by Manufacturing and Distributor Defendants' racketeering activity as described above.

833. By virtue of these violations of 18 U.S.C. § 1962(d), the Manufacturing and Distributor Defendants are liable to Plaintiff and Class members for three times the damages Plaintiff and members of the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

COUNT V

NUISANCE

(Against All Defendants)

834. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

835. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the Plaintiff and the Workers' Compensation Payors by their production, promotion, and marketing of opioids for use by the claimants of Plaintiff and the Workers' Compensation Payors.

836. Defendants' conduct and subsequent sale of its opioid products is not only unlawful but has also resulted in substantial and unreasonable interference with the public health, and the public's enjoyment of its right not to be defrauded or negligently injured.

837. Defendants' conduct is not insubstantial or fleeting. Indeed, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level, and particularly with respect to injured workers covered by Plaintiff and the Workers' Compensation Payors, that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a "crisis" and an "epidemic." It has caused deaths, serious injuries, disabilities and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

838. Defendants' conduct constitutes a public nuisance.

839. Defendants' conduct directly and proximately caused injury to Plaintiff and the Workers' Compensation Payors, as discussed *supra*.

840. Plaintiff and members of the Class have been injured by reason of Defendants' creation of the public nuisance in particularized and different form manner and degree than the public at large.

841. Plaintiff and members of the Class are entitled to recover their damages caused by Defendants' creation of this public nuisance in an amount to be determined at trial, plus costs and attorneys' fees.

COUNT VI

VIOLATION OF 720 ILCS 5/170-10.5 AND OTHER ANALOGOUS STATE INSURANCE FRAUD LAWS OR UNFAIR DECEPTIVE ACTS AND PRACTICES LAWS

(Against All Defendants)

842. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

843. Under Illinois law, "[a] person commits insurance fraud when he or she knowingly obtain, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company . . . by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made . . . intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property." 720 ILCS 5/17-10.5.

844. 720 ILCS 5/17-10.5(e)(1) provides that anyone who commits a violation of 720 ILCS 5/17-10.5 “shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self-insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained, twice the value of the property attempted to be obtained, whichever amount is greater, plus attorney’s fees.”

845. Many other jurisdictions have similar and analogous insurance fraud laws or construe their unfair deceptive acts and practices laws to extend to and prohibit the fraudulent conduct addressed in the Illinois law.

846. In carrying out the Opioid Marketing Enterprise, Defendants overstated the benefits of and evidence for the use of opioids for chronic non-cancer pain, while understating the rather serious risks of opioid use, including the risks of addiction. In disseminating such misleading information regarding the appropriateness of their opioids for certain conditions, and in falsely presenting those statements as those of independent, unbiased third-parties, Defendants made misrepresentations and omissions of material facts.

847. Indeed, Defendants directly, as well as indirectly through their control of third parties and/or aiding and abetting third parties, made and disseminated untrue, false, and misleading statements to consumers and prescribers in Plaintiff and the Workers’ Compensation Payors’ networks to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading

statements about opioids to be made or disseminated to area prescribers and consumers to promote the sale and use of opioids for treating chronic non-cancer pain.

848. Defendants also made statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. Defendants and their third-party allies repeatedly failed to disclose, or minimized, material facts about the risks, benefits and uses of opioids. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opinions false or misleading regarding the risks benefits and uses of opioids—particularly for the treatment of chronic non-cancer pain.

849. Defendants and the third parties they controlled made and disseminated such statements and material omissions through an array of marketing channels, including in-person detailing, speaker events, conferences, teleconferences, CMEs, studies, journal articles, supplements, advertisements, brochures, websites, and other patient and doctor education materials.

850. Defendants and the third-parties they controlled knew that these statements were untrue and misleading, or omitted material facts, when they made them, and knew they would likely deceive the public, and Plaintiff and members of the Class, and cause Plaintiff and members of the Class to pay out claims for prescription opioids they otherwise would not have paid for—that was the entire point.

851. This conduct directly damaged Plaintiff and the Workers' Compensation Payors, who put their trust in the physicians in their networks to appropriately convey and balance the risks and benefits of various treatment options for patients covered by their benefits programs. Physicians, in turn, are inclined to trust the advice of KOLs, front groups, and other seemingly independent sources of objective medical information. Plaintiff and the Class also put their trust in medical management vendors and third-party health care providers to review claims for medical necessity, and these groups likewise put their trust in seemingly independent sources of objective medical information to determine the appropriate standard of care. But by engaging in the conduct described herein, Defendants co-opted those sources of information in order to convince prescribing physicians—and through them, patients, Plaintiff and the Class—that opioids were medically necessary to treat chronic non-cancer pain. This was especially so given Defendants' deliberate targeting of non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate the false, deceptive, and materially misleading claims being promoted to them.

852. Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to Plaintiff and the Workers' Compensation Payors for payment. Therefore, each claim for reimbursement paid by Plaintiff and Class members for chronic opioid therapy is the direct result of Defendants' false and deceptive marketing, which presented to prescribers patently

false and deceptive information about the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain.

853. Plaintiff and the Workers' Compensation Payors only cover the cost of medical services and prescription drugs that are medically necessary and reasonably required. Doctors, pharmacists, other health care providers in Plaintiff and the Workers' Compensation Payors' networks (and agents thereof) expressly or impliedly certified to Plaintiff and the Class that opioids were medically necessary and reasonably required to treat chronic non-cancer pain, because they were influenced by the false and deceptive statements disseminated by Defendants about the risks, benefits, and superiority of opioids for treating chronic non-cancer pain.

854. Defendants caused doctors and pharmacies to submit, and Plaintiff and the Workers' Compensation Payors to pay claims that were false by: (a) causing doctors to write prescriptions for chronic opioid therapy based on deceptive representations regarding the risks, benefits, and superiority of those drugs; (b) causing doctors to certify that these prescriptions and associated services were medically necessary and/or reasonably required; and (c) distorting the standard of care for treatment of chronic pain so that doctors would feel not only that it was appropriate, but required, that they prescribe opioids long-term to treat chronic pain. Each—or any—of these factors made claims to Plaintiff and the Workers' Compensation Payors for chronic opioid therapy false.

855. These misrepresentations were material because, had Plaintiff and members of the Class known of the false statements disseminated by Defendants,

Plaintiff and members of the Class would have refused to pay for those opioid prescriptions and the attendant costs related to the patients' prescription opioid use. As such, Defendants knowingly made, used, or caused to be made, false claims with the intent to induce Plaintiff and Class members to approve and pay them.

856. As a result, Plaintiff and Class members have been injured, and Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of 720 ILCS 5/17-10.5(a)(1), as described herein.

857. Defendants knowing conduct and omissions and violations of statutes, regulations and other laws providing for the health, safety and protection of consumers and trade as set forth above further violated other interested state's insurance fraud and unfair and deceptive acts and practice laws analogous to the Illinois Consumer Fraud Act, such as, by way of example, New Jersey's Consumer Fraud Act.

858. Plaintiff and the Class members have sustained ascertainable losses and damages as result of the violation of those acts entitling them to the relief such statutes and laws provide.

COUNT VII

FRAUD

859. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

860. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to patients and prescribers as well as to Plaintiff and the Workers' Compensation Payors to induce them to purchase, administer, and consume opioids as set forth in detail above.

861. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

862. Defendants intended that Plaintiff, Workers' Compensation Payors, physicians, patients, and/or others would rely on their misrepresentations and omissions.

863. Plaintiff, Workers' Compensation Payors, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

864. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

865. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and the Workers' Compensation Payors suffered actual pecuniary damage.

866. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

867. Plaintiff and Class members are entitled to recover their damages caused by Defendants' fraud in an amount to be determined at trial.

COUNT VIII

CIVIL CONSPIRACY

868. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

869. Upon information and belief, Defendants acted in coordination with each other.

870. Defendants have knowingly conspired and agreed among themselves to deprive Plaintiff and the Workers' Compensation Payors of funds used to pay for opioid prescriptions, treatment and disability benefits under their business strategy.

871. At all times relevant to this case, Defendants conducted themselves in a manner so as to proximately cause a breach of implied duty of good faith and fair dealing as alleged in the above factual allegations contained in this complaint for damages pursuant to, and in furtherance of, the conspiracy and alleged agreement to conspire.

872. Defendants furthered the conspiracy by lending aid and encouragement to distributor, retailers, and other defendants, by ratifying and adopting the acts of the other defendants.

873. As a proximate cause of the wrongful actions or omissions committed by the Defendants, Plaintiff and the Workers' Compensation Payors have been generally damaged in the sum that exceeds the jurisdictional minimum amount but cannot yet be precisely calculated because Plaintiff and the Third-Payors continue to suffer damages every moment that the Defendants willfully conspired and agreed

among themselves to deprive Plaintiff and the Workers' Compensation Payors of funds used to pay for opioid prescriptions, treatment and disability benefits

874. All Defendants have and continue to conduct themselves maliciously by further failing to take measures to fully arrest, alleviate and abate the consequences of their tortious acts and omissions, which continue to cause harm to injured workers who have been prescribed opioid drugs and Defendants thereby continue to cause harm to Workers' Compensation Payors, as described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, in its own right, and on behalf of others similarly situated, demands judgment against Defendants jointly, severally and in the alternative for the following relief:

- (a) Certification of the matter as a class action under Rule 23b(2) for injunctive and declaratory relief;
- (b) Certification of the matter as a class action under Rule 23b(3) for monetary damages;
- (c) Certification of the matter as an issues class under Rule 23c(4)
- (d) Certification of a Workers' Compensation Payors negotiation class;
- (e) issuing notice to the Class of this action;
- (f) compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- (g) treble damages, penalties and costs;
- (h) punitive damages;

- (i) attorneys' fees
- (j) interest, costs and disbursements; and
- (k) such and further relief as this Court may deem just and proper.

Respectfully submitted,

COHEN, PLACITELLA & ROTH, P.C.



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(**Pro hac* admission to be applied for)

JS 44 (Rev. 02/19)

CIVIL COVER SHEET

19-cv-5904

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

PUBLIC SERVICE INSURANCE COMPANY

(b) County of Residence of First Listed Plaintiff Manhattan, NY
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Stewart L. Cohen, Esquire, Suite 2900, Two Commerce Square,
Philadelphia, PA 19103

DEFENDANTS

JANSSEN PHARMACEUTICALS, INC

County of Residence of First Listed Defendant Montgomery County, PA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED

Attorneys (If Known)
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II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for Nature of Suit Code Descriptions

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSJD Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS Third Party 26 USC 7609
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer w/Disabilities Employment <input type="checkbox"/> 446 Amer w/Disabilities Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 490 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes	

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity)
18 U.S.C. Section 1961

VI. CAUSE OF ACTION

Brief description of cause

Violation of RICO

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions)

JUDGE Dan Polster

DOCKET NUMBER

1:17-md-02804

DATE 12/13/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

DEC 13 2019

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 1 Park Avenue, New York, NY 10016

Address of Defendant: 1125 Trenton Harborton Road, Titusville, NJ 08560

Place of Accident, Incident or Transaction: Pennsylvania

RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when **Yes** is answered to any of the following questions:

- | | | |
|--|------------------------------|--|
| 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

I certify that, to my knowledge, the within case ☐ is / ☒ is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE 12/13/2019

Stewart L. Cohen
Attorney-at-Law / Pro Se Plaintiff

Attorney I.D. # (if applicable)

CIVIL: (Place a ✓ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☒ 11. All other Federal Question Cases
(Please specify) RICO

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury (Please specify) _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability - Asbestos
- ☐ 9. All other Diversity Cases
(Please specify) _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

Stewart L. Cohen

counsel of record or pro se plaintiff, do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs.

☐ Relief other than monetary damages is sought.

DATE: 12/13/2019

Stewart L. Cohen
Attorney-at-Law / Pro Se Plaintiff

25448

Attorney I.D. # (if applicable)

NOTE. A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38

DEC 13 2019

TJS

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CASE MANAGEMENT TRACK DESIGNATION FORM

Public Service Insurance Company

CIVIL ACTION

v.

Janssen Pharmaceuticals, Inc.

19

5904
NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1.03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security - Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (x)
- (f) Standard Management Cases that do not fall into any one of the other tracks. ()

12/13/2019	<i>Shawn L. Cohen</i>	Plaintiffs
Date	Attorney-at-law	Attorney for
215-567-3500	215-567-6019	scohen@cpirlaw.com
Telephone	FAX Number	E-Mail Address

(Civ. 660) 10/02

DEC 13 2019